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ABSTRACT

The text of a Congressional hearing considering limitations on the dispensing of drugs by physicians for profit is presented in this document. It focuses in particular on H.R. 2093, a bill introduced by Representative Ron Wyden which would generally prohibit physicians and other practitioners from directly profiting from the sale of drugs which they have prescribed. The text of H.R. 2093 is included. Testimony by these witnesses is included: (1) Larry L. Braden, American Pharmaceutical Association; (2) Nancy W. Dickey, chairman, Council on Ethical and Judicial Affairs, American Medical Association; (3) Richard L. Fields, president, Medical Society of Virginia; (4) Charles A. Hampton, Competitive Health Care Coalition; (5) James Krahulec, National Association of Chain Drug Stores; (6) Daniel Oliver, Chairman, Federal Trade Commission; (7) Robert H. Taylor, president, American Academy of Family Physicians; (8) Michael P. Weinstein, pediatrician, Fort Valley, Georgia; (9) Charles West, executive vice president, National Association of Retail Druggists, and (10) Jeffrey Zuckerman, director, Bureau of Competition, Federal Trade Commission. Additional materials submitted for the record by the National Association for Ambulatory Care and Parnell Pharmaceuticals, Inc. are included. (ABL)

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PHYSICIAN DISPENSING OF DRUGS

HEARING

BEFORE THE

SUBCOMMITTEE ON
HEALTH AND THE ENVIRONMENT

OF THE

COMMITTEE ON
ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONF HUNDREDTH CONGRESS

FIRST SESSION

ON

H.R. 2093

A BILL TO AMEND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT TO LIMIT THE DISPENSING OF CERTAIN DRUGS BY PRACTITIONERS

APRIL 22, 1987

Serial No. 100-36

Printed for the use of the Committee on Energy and Commerce

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CONTENTS

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PHYSICIAN DISPENSING OF DRUGS

WEDNESDAY, APRIL 22, 1987

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH AND THE ENVIRONMENT,
Washington, DC.

The subcommittee met, pursuant to notice, at 1:35 p.m., in room 2123, Rayburn House Office Building, Hon. Henry A. Waxman (chairman) presiding.

Mr. WAXMAN. The hearing will come to order.

This afternoon, the subcommittee will be considering limitations on the dispensing of drugs by physicians for profit. In particular, we will be discussing H.R. 2093, introduced by Mr. Wyden, which would generally prohibit physicians and other practitioners from directly profiting from the sale of drugs which they have prescribed.

In an editorial on March 28, 1987, under the heading, "Doctors Shouldn't be Pharmacists," the New York Times posed the difficult questions we will be facing today.

The physician/pharmacist has an obvious potential conflict of interest. Might he be tempted to write unnecessary prescriptions or to prescribe a drug he sells when another he doesn't sell might be preferable, or to sell brand name drugs with high markups when cheaper generics are available?

These questions go directly to the ethics of medical practice. In our fee-for-service system, the immediate financial incentives favor any service with its own fee. But the question before us now is whether there is something different when it comes to the simple act of prescribing a drug.

This hearing does not offer us simple questions, and we do not expect simple answers. We do hope that our panelists today will help us understand the situation better and determine the appropriate course of action.

Before we introduce our first witness, I would like to recognize our colleagues on the subcommittee, and I want to call on first the author of H.R. 2093, our colleague, Mr. Wyden.

Mr. WYDEN. Mr. Chairman, for the past several years, according to former American Medical Association president, Dr. Harrison Rogers, physicians have been bombarded with advertisements touting an easy way to extra income—selling prescription drugs to their patients for a profit. One such solicitation reads: "How to Earn $52,000 This Year with No Investment." Another asks: "Why pass the buck. Every time you sign a prescription, it's like writing a check to the pharmacy."

Promoting these sales is the drug repackaging industry which buys drugs in bulk and markets them to physicians for resale. James R. Roberts, president of a Missouri repackaging firm, recently told Stock Market Magazine that doctors' office sales represent, and I quote, "a potential $20.3 billion industry. Currently only 5 percent of the Nation's 500,000-plus practicing physicians dispense. I see that increasing to some 50 percent in the next 5 to 7 years. The trend has already begun, and the money is rolling in."

Mr. Roberts' own firm, Direct Pharmaceuticals Corporation, went public in November of 1985 at $3 a share and already trades in the $8.50 to $9 range. Is it any wonder that a major investment banking house called my office yesterday to inquire about the bill before us today?

While the field may present a terrific investment opportunity, this one-stop drug shopping poses a serious conflict of interest. Doctors selling drugs to patients may succumb to financial enticement by overprescribing or prescribing a drug they have in stock, regardless of whether it's the most appropriate treatment.

Price gouging is already occurring. In Oregon, the Medical Director of a health insurer recently recommended reduced reimbursement for some drug claims after finding that some doctors were marking up prescription drugs by 200 percent or more. Dr. Bob Loomis, an experienced Eugene, OR physician said recently: "I know how much penicillin costs. A fair market price won't allow a 200 percent markup."

Prominent members of the medical profession believe that the temptation to put profit first and patient care second is inherent in physician sales. Dr. Arnold Relman, editor of the New England Journal of Medicine notes that "doctors selling drugs is not in the patient's best interest." His colleague, Dr. Arthur Kaplan of the Hastings Center, has said that "any benefit in physician sales is outweighed by the threats to a vulnerable group of consumers."

Speaking for the American Medical Association several weeks ago, Dr. Rogers seemed to agree. He said, "The practice of physicians selling drugs to their patients would," and I quote, "make doctors pharmacists and create a conflict of interest."

But despite their stated opposition to the practice of physician sales, the AMA now opposes my legislation to limit the practice.

Why? The AMA believes that Federal legislation is unnecessary and that this is a State issue. They are simply incorrect. They are wrong, because the Federal Trade Commission is actively trying to stop States from limiting physician sales. The FTC believes that doctors selling drugs promotes competition. Consequently the Commission claims that limiting such sales may violate the Federal antitrust laws, and the Federal Trade Commission is aggressively imposing its point of view on the States.

Look what happened recently when the Georgia Board of Pharmacy moved to bring physicians who sell drugs under similar regulations as pharmacists. The FTC Bureau of Competition Director, Jeffery Zuckerman, wrote the Georgia Board that their action would "impose discriminatory restraints on practitioner dispensing and may place the Board at risk under the Federal antitrust laws."

The facts are clear. Because of the FTC's position, Congress must act to limit physician sales, or they simply won't be regulated at all.

True competition in the medical care should enhance the quality of c. re, not compromise it. I don't see much competition when a doctor writes a prescription from one side of the desk and then sells it from the other. There is no free marketplace inside one doctor's office.

The Federal Government has long recognized the dangers posed by an unregulated drug industry. In 1938, the Congress passed the Federal Food, Drug, and Cosmetic Act to protect the market from unsafe products and practices. That Act has overseen every detail of the drug manufacturing and distribution system in this country for nearly half a century.

Mr. Chairman, because the FTC has made it virtually impossible for the States to act in this crucial area, and because drugs have traditionally been the subject of Federal regulation, we should enact H.R. 2093. The bill, of course, limits physicians' abilities to sell drugs.

But I certainly agree with the American Medical Association that it may be appropriate in some cases for doctors to sell drugs, and my bill spells out what those situations are.

Mr. Chairman, I thank you for holding this important hearing, and I would conclude by saying that Dr. Bob Loomis, the Eugene physician and a longtime member of the American Medical Association, has summed up the question before us today very well. He said: "Should physicians be allowed to profit from drugs?" And answered: "I don't think that they should."

Dr. Loomis is right, as Oregonians usually are, and it's time to pass H.R. 2093, and I thank you for your consideration.

Mr. WAXMAN. Thank you, Mr. Wyden. These are letters from Oregonians on the other side of the issue.

We are pleased to now recognize the very distinguished member of our subcommittee, Mr. Whittaker, for comments he wishes to make.

Mr. WHITTAKER. Thank you, Mr. Chairman.

I welcome the opportunity to continue to explore this issue. As I understand it, this is the second hearing in two weeks.

I would just like to comment that I hope that the panel that we are going to hear from today is truly balanced and will give us both sides of the issue. While I personally tend to agree in principle, I have some very grave reservations about the impact of this proposed legislation on areas which I represent, namely that being rural areas. I am aware that the author has tried to make an exemption to this restriction if a practitio r's office is located more than 15-miles from a pharmacy. I don't see that being adequate particularly, if the resident may be a sole resident within the residence and certainly may not be able to either physically or mentally be able to transport himself or herself to the physician's office to get that prescription filled and return.

I guess I just have a question as to whether this is really a growing problem in the country or if it is a localized problem, and if it is localized and not particularly growing whether we need to provide Federal oversight in this area or certainly to restrict the avail-

ability of delivery of health care to the extent that this bill proposes to do.

So I'm looking forward to hearing the witnesses, and I'm hopeful that I'll be more enlightened. But I would have to be very candid in saying I have some very grave reservations at this time.

Mr. WAXMAN. Thank you, Mr. Whittaker.

Mr. Bates, any opening comments?

Mr. BATES. I'm glad that we're having hearings on this. At first blush, I felt perhaps there is a conflict. Now I'm more concerned that there is a case of overcharging or gouging by doctors, but I think that will come out in the hearing

I certainly think that the cost overruns in the health care industry in general are of serious concern. I'm just curious in terms of the perspective of all the other problems we face, if this is the most serious one in terms of whether the doctors are overcharging on a prescription. I know, myself, I prefer to get the prescription filled with the doctor rather than having to go to the pharmacy. But I also understand there are some competitive forces as more and more prepackaging drugs are dispensed by doctors. I think that may be hurting the pharmacies, and I'd like to see and hear some information with respect to that part of the issue.

Mr. WAXMAN. Thank you very much.

Mr. Fields.

Mr. JACK FIELDS. Yes, Mr. Chairman, just very briefly. I'm glad that we're having this hearing today. I cannot say that I'm glad we're having a markup tomorrow morning on this same issue, and I have to ask myself the question: Why the rush to legislate? Why not afford us the time to digest and understand the complex testimony that we're going to be hearing today, particularly when we are going to be entering an area that has heretofore been a State province? And I just have to ask myself: Is there proof that States are not doing a good job in this particular area?

And I think that, as a committee, we should feel positive as to the effects of this legislation before we seek to micromanage and abrogate the rights of States to set their own standards and their procedures in regard to health professionals.

Mr. WAXMAN. Thank you, Mr. Fields.

Mr. Walgren, do you have any comments?

Mr. WALGREN. Well, I'd just like to add that I do think this hearing is especially important. This is an interesting question, because it came on to most of us, I think, or certainly myself as a question of first impression, and there certainly have turned out to be two very real sides to this.

I, myself, am particularly concerned that this could create an incentive to overprescribe or prescribe perhaps a little bit off the mark if it is a drug that the doctor may or may not have in the office.

At the same time, I am very reluctant to walk away from the efficiencies and the good will that physicians can and, I think, should create for themselves in the dispensing of drugs in the office. I know that in our own circumstances the convenience of receiving drugs in the office, as opposed to making that second stop with a sick child, is something that is very real, and there are real efficiencies and changes in the way that drugs are able to be pro-

vided to the population as a whole, and I think those are very real considerations.

So I want to say, I have an open mind on this. I'm interested in the extent of the problem and the comments the witnesses might be able to shed on the particular concerns that I have, and I know that as a Congress we have an awful lot to learn about the issue.

Thank you, Mr. Chairman.

[The text of H.R. 2093 follows:]

I

100TH CONGRESS
1ST SESSION

H. R. 2093

To amend the Federal Food, Drug, and Cosmetic Act to limit the dispensing of certain drugs by practitioners.

IN THE HOUSE OF REPRESENTATIVES

APRIL 9, 1987

Mr. WYDEN introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to limit the dispensing of certain drugs by practitioners.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. DISPENSING LIMITS.

Section 503 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353) is amended by adding at the end the following:

"(c)(1) Except as provided in paragraph (2), no practitioner licensed by law to administer drugs (hereinafter referred to as a 'practitioner') may dispense for profit a drug

which is subject to subsection (b), which is to be orally administered, and which is not a vaccine.

"(2) Paragraph (1) does not apply to the dispensing of a drug—

"(A) for emergency medical reasons,

"(B) by a practitioner in an office which is located more than 15 miles from a pharmacy, or

"(C) by a practitioner in a community health center receiving support under section 330 of the Public Health Service Act, in a rural health clinic as defined by section 1861(aa)(2) of the Social Security Act, or in an Indian health clinic operated by the Indian Health Service or under the Indian Self-Determination Act.

"(3) For purposes of this subsection, the term 'dispense' means the delivery of a drug to an ultimate user by a practitioner or through a pharmacy pursuant to a prescription of a practitioner.".

SEC. 2. EFFECTIVE DATE.

The amendment made by section 1 shall take effect 180 days after the date of the enactment of this Act.

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Mr. WAXMAN. Let's proceed to hear from some witnesses and see if we can get some of these issues clarified.

I would like to call our first panel forward, Daniel Oliver, Chairman of the Federal Trade Commission and Dr. Nancy Dickey, chairman of the AMA's Council on Ethical and Judicial Affairs. Please come forward and take seats at the table.

We are pleased to welcome you to our subcommittee hearing this afternoon. I'd like to mention that your prepared statements will be made part of the record in full. We request that you try to summarize those statements within 5 minutes.

Mr. Oliver, why don't we start with you? Would you pull the microphone closer to you? There is a button on the base that will turn on the mike.

STATEMENTS OF DANIEL OLIVER, CHAIRMAN, FEDERAL TRADE COMMISSION, ACCOMPANIED BY JEFFREY ZUCKERMAN, DIRECTOR, BUREAU OF COMPETITION; AND NANCY W. DICKEY, CHAIRMAN, COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, AMERICAN MEDICAL ASSOCIATION

Mr. OLIVER. Thank you, Mr. Chairman. Mr. Chairman and members of the subcommittee, I appreciate this opportunity to present my views with respect to H.R. 2093 which would prohibit the dispensing of prescription drugs by physicians except in extremely limited circumstances.

Before turning to my specific concerns, let me state that although the views I express today are my own, the Commission is unanimous in opposing enactment of H.R. 2093. I would also like to discuss with the subcommittee more generally some of the concerns that have been raised about physician dispensing.

Although the stated rationale for the proposed prohibition of physician dispensing is consumer protection, I believe that it would injure the American people by unnecessarily restricting their options as consumers. Moreover, considering the traditional role of the States in regulating both physicians and pharmacists, there does not appear to be any reason at all for any Federal regulation of physician dispensing, let alone a Federal ban.

Physician dispensing of prescription drugs has been permitted by decades by the vast majority of States. It was once quite common. Recently, health care markets have become more competitive and more responsive to consumer demand and physician dispensing is again becoming more widespread.

The survival of physician dispensing puts competitive pressure on retail pharmacies, pressure to provide the mix of prices, quality and services that their customers want, just as the growth of HMO's, ambulatory care centers and other non-traditional types of medical practices put competitive pressure on physicians in traditional practices.

I'm not here today to suggest that physician dispensing is preferable to pharmacists dispensing or vice versa but rather to argue in favor of consumer choice. Some patients may prefer the mix of price, quality and service provided by pharmacists. Others may prefer to obtain their prescription drugs more conveniently at their

physician's office. Indeed, the same patient may have different preferences at different times.

For example, a parent with a 2-year-old child suffering the pain of an ear infection may desire one stop shopping whereas the same parent might prefer prescription vitamins for the child at a pharmacy.

Those who would restrict consumer choice should be required to demonstrate that permitting choice has harmful effects that physician dispensing in[illegible] the public health and safety and that more carefully targeted [illegible] and safety regulations cannot protect the public from such harm. That burden has not been met here.

Two arguments offered to support eliminating physician dispensing. The first is that physician dispensing presents an inherent conflict of interest. That is, physicians may over prescribe drugs or limit product selection to their current inventory in order to serve their own financial interests.

The second argument is that any mistakes physicians may make would not be caught if pharmacists did not act as a check when they dispense medication.

As I have discussed in more detail in my prepared testimony, neither of these arguments presents a compelling case for prohibiting physician dispensing. A physician's incentive to abuse dispensing authority for financial gain is the same conflict that arises whenever a physician orders any service he provides himself, even follow-up visits. Indeed, it is identical to the conflict faced by every provider of expert services who recommends a product and then offers to supply it.

Familiar examples include stock brokers, who recommend investments, and auto mechanics who recommend new brakes. Even pharmacists face this problem when they recommend vitamins or other over the counter drugs. Banning an entire category of transactions that consumers may want is not the ultimate way to deal with this problem. In general, the best way to deal with this problem is to encourage competition, not to restrict it. Competitors of those with the potential conflict of interest have every incentive to educate consumers. If any regulation is necessary, potential abuses can be dealt with by more precisely targeted measures such as discipline by professional licensing boards and other State enforcement of health and safety regulations.

In response to the argument that pharmacist dispensing provides superior care, I have two points. First, dispensing physicians are in a position to provide many of the same services that pharmacists do, except for being a check on themselves. More important, the fact that pharmacists provide valuable services, including the check function, does not provide a basis for government to preclude consumers from deciding to obtain their prescription drugs from their physicians.

A Federal ban, moreover, seems particularly inappropriate. Historically, State legislatures and agencies have set standards for the practice of medicine. The Federal Government should no more prescribe in this area of health and safety than it should regarding a safe driving speed. What is suitable for Arizona, after all, may be unsuitable for New York.

Contrary to what Mr. Wyden suggested, the FTC would in no way interfere with State legislation.

Mr. Chairman, to me, this looks like special interest legislation for the benefit of pharmacists, as I think the picture on the front of Drug Store News makes plain. Accordingly, I urge the subcommittee not to approve H.R. 2093.

Thank you again for this opportunity to present my views. I'd be happy to answer any questions you may have.

[The prepared statement of Mr. Oliver follows:]

STATEMENT OF DANIEL OLIVER

Good morning Mr. Chairman and members of the subcommittee: I appreciate this opportunity to present my views with respect to H.R. 2093, which would prohibit the dispensing of prescription drugs by physicians, except in extremely limited circumstances. Before turning to my specific concerns, let me just state that although the views I express today are my own, the Commission is unanimous in opposing enactment of H.R. 2093. I would also like to discuss with the subcommittee more generally some of the concerns that have been raised about physician dispensing. Although the stated rationale for the proposed prohibition of physician dispensing is consumer protection, I believe that it would injure the American people by unnecessarily restricting their options as consumers. Moreover, considering the traditional role of the States in regulating both physicians and pharmacists, there does not appear to be any reason at all for any *Federal* regulation of physician dispensing, let alone a Federal ban.

Physician dispensing of prescription drugs has been permitted for decades by the vast majority of States, and it was once quite common. In the past, this practice has been most important to consumers in rural areas. More recently, as health care markets have become more competitive, and therefore more responsive to consumer demand for additional services and greater convenience, physician dispensing is again becoming more widespread. Further growth is projected, particularly at non-traditional types of health care facilities. The recent growth of physician dispensing puts competitive pressure on traditional retail pharmacies—pressure to provide the mix of prices, quality, and services their customers want—just as the growth of HMO's ambulatory care centers, and other non-traditional types of medical practices puts competitive pressure on physicians in traditional practices.

As a general rule, consumers benefit when they can choose from a wide array of options. This rule applies with equal force when it comes to health care generally, or the provision of medicines in particular. Some patients may prefer the mix of price, quality, and service provided by pharmacists. Others—particularly the elderly, or parents of young children—may prefer to obtain their prescription drugs more conveniently at their physician's office. Indeed, the same patient may have different preferences at different times. A parent with a 2-year-old child suffering the pain of an ear infection may desire one-stop shopping, whereas the same parent might prefer to get prescription vitamins for the child at a pharmacy. And patients who choose to obtain an initial prescription from their physician may choose to obtain follow-up prescriptions from traditional or mail order pharmacies. Competition among physicians and pharmacists provides a strong incentive for members of both professions to offer the best combination of price, quality, and service—best from their patients' perspectives.

I am not here today to suggest that physician dispensing is preferable to pharmacist dispensing, or vice-versa, but, rather, to argue in favor of consumer choice. Those who would restrict consumer choice should be required to demonstrate that permitting choice has harmful effects. That burden has not been met here. Absent reliable evidence that physician dispensing injures the public health and safety, and that more carefully targeted health and safety regulations could not protect the public from such harm, a prohibition of physician dispensing is likely to promote only the private economic interests of pharmacists, retail druggists, and physicians who compete with non-traditional types of medical practices.

Two arguments are offered to support eliminating physician dispensing. The first is that physician dispensing presents an inherent conflict of interest. That is, physicians may overprescribe drugs or limit product selection to their current inventory in order to serve their own financial interests. The second argument against physician dispensing is that any mistakes physicians may make will not be caught if pharmacists do not act as a "check" when they dispense medications.

The possibility that physicians will over-prescribe drugs or limit product selection in order to increase their revenues does not provide a basis for denying consumer choice. A physician's incentive to abuse dispensing authority for financial gain is the same conflict that arises whenever a physician orders any service he provides himself, whether lab work, x-rays, allergy shots, or even follow-up visits. Indeed, the potential conflict of interest inherent in physician dispensing is identical to the conflict faced by every provider of expert services who recommends a product and then offers to supply it. Familiar examples include stockbrokers who recommend investments and auto mechanics who recommend new brakes. Even pharmacists face this problem when they recommend vitamins or other over-the-counter drugs.

There are several ways to deal with this type of problem. Rarely, however, if ever, is banning an entire category of transactions that many consumers may want the optimal solution. As a general proposition, the best way to deal with this type of problem is to encourage competition, not to restrict it. Competitors of those with the potential conflict of interest have every incentive to provide information to consumers, in order to enable those consumers to make informed, rational choices. For example, the arguments that pharmacists are making to Congress now about why the American people should not be permitted to obtain prescription drugs from physicians, should be made instead to the American people. We should all have confidence in the ability of the American people to decide what is best for themselves, if given the information necessary to make intelligent choices.

Moreover, if for some reason it is believed that in deciding where to obtain their prescription drugs, the American people are not capable of weighing adequately the potential conflicts of interest faced by physicians, it would seem more appropriate to employ measures more precisely targeted at potential abuses, such as discipline by professional licensing boards and other State enforcement of health and safety regulations. That approach at least does not ban an entire category of legitimate transactions simply in order to prevent some potential abuses.

The second argument against physician dispensing is essentially that dispensing by pharmacists provides superior patient care because pharmacists may detect prescribing errors, identify potential adverse allergy and drug interactions, and provide patient counseling. There are two responses to this argument. In the first place, physician dispensing does not necessitate the loss of these benefits. Under State law, physicians are responsible for their prescribing choices. By virtue of their contact with the patient at the time of prescribing, physicians are in an excellent position to assess the possibility of allergic reactions or dangerous drug interactions, and to provide any necessary counseling. In many States, physicians who dispense are required to meet the safety and health standards applicable to dispensing by pharmacists, including standards with respect to the use of support personnel, record keeping, labeling, and packaging.

In the second place—and more important—the fact that pharmacists do provide valuable services does not mean that the Federal Government should preclude consumers from choosing to buy prescription drugs from their physicians instead. If pharmacists believe that the dispensing physicians, they should educate consumers, through advertising and point-of-sale materials, about the price and quality of their services. Consumers should be free to choose between the price, quality, and service options offered by both professions.

For these reasons, it would hurt, not protect, consumers if physician dispensing were banned. A *Federal* ban, moreover, seems particularly inappropriate. Historically, State legislatures and agencies have set standards for the practice of medicine. There is no apparent need for Federal regulation in this area. We are aware of no evidence that the States are incapable of carrying out law enforcement with respect to physician dispensing in order to protect public health and safety. All but a few States have made the judgment to permit physician dispensing. Many States have established health and safety standards for physicians who dispense that are intended to protect consumers while permitting them to exercise a choice among providers of prescription drugs. Many also have enacted statutes that prohibit physicians from exploiting patients for financial gain. We do not oppose State laws or regulations that require physicians who dispense to meet the same reasonable safety and health standards that are applicable to pharmacists, but the Federal Government should no more prescribe in this area of health and safety than it should regarding a safe driving speed. What is suitable for Arizona, after all, may be unsuitable for New York.

Physician dispensing has been around for a long time, without our having seen any reliable evidence that it presents a threat to public health or safety. It does pose a competitive threat to traditional pharmacies by offering an alternative source of medicines to the American people, but that is hardly the sort of "threat"

that should be banned by Congress. In the absence of evidence that physician dispensing is jeopardizing public health and safety, and that the public cannot be protected by State safety and health regulation, a Federal law prohibiting physician dispensing would be a prime example of unnecessary. heavy-handed, anti-consumer government regulation. It would be harmful to consumers because it would limit consumer choice, restrain competition among physicians and pharmacists, and reduce the incentives for physicians and pharmacists to offer better combinations of prices, quality, and services. Such a restriction of consumer choice would benefit only the private economic interests of pharmacists, retail drug stores, and those physicians who are facing increased competition from non-traditional types of medical practices. it would seriously disserve the public interest. Accordingly, I urge the subcommittee not to approve H.R. 2093.

Thank you again for this opportunity to present my views. I would be happy now to answer any questions you may have.

Mr. WAXMAN. Thank you very much, Mr. Oliver. Dr. Dickey, we would like to hear from you.

STATEMENT OF NANCY W. DICKEY

Ms. DICKEY. Mr. Chairman and members of the committee, my name is Nancy Dickey. I'm a family physician in Richmond, TX and I'm also the chairman of the council on ethical and judicial affairs of the American Medical Association. Accompanying me is Thomas Wolff of the AMA's Department of Federal Legislation and Nancy Bannon of the AMA's Department of State Legislation.

The AMA is pleased to have the opportunity to testify before this committee concerning the issue of physician drug dispensing and pharmacists prescribing. The AMA through our Council on Ethical and Judicial Affairs, has examined the issue of physician dispensing and has concluded that physicians should avoid regular dispensing and retail sale of drugs, devices or other products, when the needs of patients can be met adequately by local ethical pharmacies or suppliers.

However, the Council has also stated that circumstances exist in which physicians may ethically dispense drugs. While no official figures are available concerning how many physicians currently dispense prescription drugs to their patients for a profit, the practice does not appear to be widespread.

For example, pharmaceutical industry officials estimate that only 5 percent of the physicians in the New York/New Jersey/Connecticut area routinely dispense drugs.

Mr. Chairman, we have seen no demonstrated need for Federal legislation to regulate physician dispensing. In addition, such a sweeping response may carry unintended negative results by limiting physician dispensing activity that benefits patients. Patients in rural areas would stand to be the most disadvantaged by unnecessary Federal restriction on dispensing but there are many other exceptions that could also be presented for you.

Representative Wyden has introduced legislation, H.R. 2093, that would amend the Federal Food, Drug and Cosmetic Act to prohibit in most cases the dispensing of drugs by practitioners licensed to administer drugs. The AMA opposes Federal legislation that would regulate dispensing or prescribing. Such legislation would constitute inappropriate intrusion into an area properly subject to State regulation and it might ignore the real differences and circumstances from State to State.

We believe strongly that any regulation to the practice of medicine including physician dispensing, should continue to be left to the States. States are in the best position to determine whether statutes or regulations restricting physician dispensing are needed and to design and enforce any restrictions imposed on physician dispensing. The need for sweeping Federal legislation to prohibit physician dispensing has not been established and if a major problem does develop, measures much less injurious to patients could be utilized to ensure that patients are not economically exploited.

For example, physicians could be encouraged or even required by States to inform their patients that they have the right to have their prescriptions filled wherever they choose. After such full disclosure, if a patient for whatever reason wants to have a prescription filled by his or her physician, why should the Federal Government prevent this?

In some parts of the country, particularly rural areas, physician dispensing is essential to providing quality patient care. In such areas, the nearest pharmacy is often many miles away. H.R. 2093 attempts to address this problem by allowing a physician to dispense drugs if there is no pharmacy within 15 miles of his office.

However, the bill fails to address the needs of patients to whom it would be a major inconvenience to have their prescriptions filled at a pharmacy, even though one might be available within the 15 miles of the office. Examples are patients with very ill or uncomfortable children; geriatric patients to whom multiple stops are a great inconvenience and in fact, sometimes such an inconvenience that they go home without filling the prescriptions they receive.

We are concerned that such a proposal can actually serve to discourage more patients from having their prescriptions filled and lower the quality of care in rural areas or for specific groups of patients.

In conclusion, Mr. Chairman, the AMA believes that physicians should avoid the regular dispensing of drugs where the needs of their patients can be filled by local ethical pharmacies. We also believe that pharmacists should not prescribe drugs for their patients but the AMA opposes Federal legislation that would restrict physician dispensing and ignore the local needs. Drug dispensing traditionally and properly has been the subject of State regulation. The need for such Federal legislation has not been established and our greatest concern is that such legislation could have a negative effect on patient care and quality of care, particularly our patients in the rural areas.

Mr. Chairman, I'll be happy to answer any questions members of the committee may have.

[Testimony resumes on p. 37.]

[The prepared statement of Ms. Dickey and attachment follow:]

STATEMENT

of the

AMERICAN MEDICAL ASSOCIATION

to the

Subcommittee on Health and the Environment
Committee on Energy and Commerce
United States House of Representatives

Presented by

Nancy W. Dickey, M.D.

RE: Physician Drug Dispensing
and Pharmacist Prescribing

April 22, 1987

Mr. Chairman and Members of the Committee:

My name is Nancy W. Dickey, M.D. I am a family practitioner in Richmond, Texas. I am also the Chairman of the Council on Ethical and Judicial Affairs of the American Medical Association. Accompanying me is Thomas Wolff of the AMA's Department of Federal Legislation.

The AMA is pleased to have the opportunity to testify before this Committee concerning the issue of physician drug dispensing and pharmacist prescribing.

The AMA, through our Council on Ethical and Judicial Affairs, recently examined the issue of physician dispensing and concluded that physicians should "avoid regular dispensing and retail sale of drugs,

devices or other products when the needs of patients can be met adequately by local ethical pharmacies or suppliers." However, the Council also stated that circumstances exist in which physicians may ethically dispense drugs. A copy of the Council's report is attached to our statement.

Subsequently, our Association, the National Association of Retail Druggists and the National Association of Chain Drug Stores issued the following joint statement:

> The National Association of Retail Druggists, the American Medical Association and the National Association of Chain Drug Stores each believe that the traditional checks and balances provided by a system authorizing physicians to prescribe and pharmaciats to dispense prescribed medications best serve the public health and welfare of the consumer. Individual physicians and pharmacists must make their own decisions on this issue based on applicable laws and the health needs of their patients.

The practice of physician dispensing has fluctuated over the years. Unofficial figures show that in 1947, almost one-quarter of all physicians dispensed pharmaceuticals. By 1967, the percentage of physicians who dispensed had declined to only 10%.

While no official figures are available concerning how many physicians currently dispense prescription drugs to their patients for a profit, physician dispensing does appear to be increasing in recent years. The practice, however, does not appear to be widespread. For example, pharmaceutical industry officials estimate that only 5% of the physicians in the New York-New Jersey-Connecticut area dispense drugs.

Mr. Chairman, we have seen no demonstrated need for federal legislation to regulate physician dispensing. In addition, such a sweeping response may carry unintended results by also limiting physician

dispensing activity that benefits patients. Patients in rural areas would stand to be the most disadvantaged by an unnecessary federal restriction on physician dispensing.

Wyden Amendment

Congressman Wyden (D-OR) has proposed a drug dispensing amendment (Wyden Amendment) that would modify the Federal Food, Drug, and Cosmetic Act to prohibit a "practitioner licensed by law to administer drugs" from dispensing "for profit" an "orally administered" prescription drug. Exceptions would be permitted for cases where the physician is more than 15 miles from the nearest pharmacy, or if the physician is in a community health center, rural health clinic or a clinic operated by the Indian Health Service. While exceptions also would be allowed for "emergency medical reasons," the term is not defined.

The AMA opposes the Wyden amendment as well as other federal legislation that would regulate dispensing or prescribing. Such legislation would constitute an inappropriate intrusion into an area properly subject to state regulation and would ignore real differences in circumstances between states. Our greatest concern is that the Wyden amendment could have a particularly negative effect on the quality of patient care in rural areas, other areas not served by an ethical pharmacy, and in instances where patients clearly would benefit from immediate dispensing.

State Versus Federal Regulation

We believe strongly that any regulation of the practice of medicine, including physician dispensing, should continue to be left to the

states. We queation the basis for federal intervention into the practice of medicine, especially with respect to private transactions in which no federal interest is directly involved. Such invclvement would establish a negative precedent for even greater federal intrusion in the practice of medicine. The Federal Food, Drug, and Cosmetic Act is intended to regulate the manufacturing and marketing of drugs to assure their safety and efficacy. It is not intended, and should not be used, to regulate the practice of medicine.

States are in the best position to determine whether statutes or regulations to regulate physician dispensing are needed and to design and enforce any restrictions imposed on physician dispensing.

During 1986, one-third of the states considered measures to regulate physician dispensing of controlled substances, legend drugs, and/or drug samples. These efforts included proposals to prohibit all dispensing, to prohibit dispensing of drug samples, to restrict dispensing of certain drug classes, and to strengthen recordkeeping and labeling requirements. This activity shows that states are addressing this issue. While many states have considered measures to regulate physician dispensing, state regulation to restrict physician dispensing has been minimal.

The need for sweeping federal legislation to prohibit physician dispensing has not been established. If a major problem does develop, measures less injurious to patients could be utilized to ensure that they are not economically exploited. For example, physicians could be encouraged, or even required, by states to inform their patients that they have the right to have their prescription filled wherever they

choose. After such full disclosure, if a patient for whatever reason wants to have a prescription filled by his or her physician, why should the federal government prevent this?

Rural Area Concerns

In some parts of the country - particularly in rural areas - physician dispensing is essential to providing quality patient care. In such areas, the nearest pharmacy is often many miles away. The Wyden amendment attempts to address this problem by allowing a physician to dispense drugs if there is no pharmacy within 15 miles of his office. However, the amendment fails to address the needs of patients to whom it would be a major inconvenience to have their prescription filled at a pharmacy even though one is within 15 miles of their physician's office. We are concerned that the Wyden amendment actually could serve to discourage some of these patients from even having their prescription filled and thereby lower the quality of care in rural areas.

Conclusion

The AMA believes that physicians should avoid regular dispensing of drugs where the needs of their patients can be met adequately by local, ethical pharmacies. We also believe that pharmacists should not prescribe drugs for patients.

The AMA opposes federal legislation that would restrict physician dispensing and ignore local needs. Drug dispensing traditionally and properly has been the subject of state regulation. The need for such federal legislation has not been established. Finally, our greatest concern is that such legislation could have a negative effect on patient care and particularly on our patients in rural areas.

Mr. Chairman, I will be happy to answer any questions Members of the Committee may have.

REPORT OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS

Report: A
(I-86)

Subject: Conflicts of Interest

Presented by: Nancy W. Dickey, M.D., Chairman

Referred to: Reference Committee on Amendments to Constitution and Bylaws
(David B. Horner, M.D., Chairman)

At its 1985 Interim Meeting, the House of Delegates adopted Substitute Resolution 18 which requested the Council on Ethical and Judicial Affairs "to continue to review its 1984 Conflict of Interest Guidelines and to amplify them as needed to address current and emerging situations relating to financial interests of physicians in organizations involved in the provision of medical services." In addition, Board of Trustees Report GG (I-85) on "Integration of the Health Care Sector: Definitions, Trends and Implications" informed the House that the Council on Ethical and Judicial Affairs would "continue to study and suggest means by which physicians may distinguish conflict of interest situations...and further refine its guidelines for their resolution." The House of Delegates adopted the Council's Conflict of Interest Guidelines at its 1984 Interim Meeting (Judicial Council Report C, I-84). The Council's position is:

Physician ownership interest in a commercial venture with the potential for abuse is not in itself unethical. Physicians are free to enter lawful contractual relationships, including the acquisition of ownership interests in health facilities or equipment or pharmaceuticals. However, the potential conflict of interest must be addressed by the following:

1. the physician has an affirmative ethical obligation to disclose to the patient or referring colleagues his or her ownership interest in the facility or therapy prior to utilization;

2. the physician may not exploit the patient in any way, as by inappropriate or unnecessary utilization;

Past House Action: A-86:246;I-85:100-109,231;I-84:175

3. the physician's activities must he in strict conformance with the law;

4. the patient should have free choice either to use the physician's proprietary facility or therapy or to seek the needed medical services elsewhere; and

5. when a physician's commercial interest conflicts so greatly with the patient's interest as to be incompatible, the physician should make alternative arrangements for the care of the patient.

The Council promulgated these guidelines to supplement its opinion on "Health Facility Ownership by Physician" which provides:

> A physician may own or have a financial interest in a for-profit hospital, nursing home or other health facility, such as a free-standing surgical center or emergency clinic. However, the physician has an affirmative ethical obligation to disclose his ownership of a health facility to his patient, prior to admission or utilization.
>
> Under no circumstance may the physician place his own financial interest above the welfare of his patients. The prime objective of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration. For a physician to unnecessarily hospitalize a patient or prolong a patient's stay in the health facility for the physician's financial benefit would be unethical.
>
> If a conflict develops between the physician's financial interest and the physician's responsibilities to the patient, the conflict must be resolved to the patient's benefit. (Section 4.05, CURRENT OPINIONS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, 1986)

The principle of resolving conflicts to the patient's benefit is derived from the physician's role as a fiduciary, i.e., a person who, by his undertaking, has a duty to act primarily for another's benefit in matters connected with that undertaking. The ethical issue for the physician is how to resolve conflicts of interest to the patient's benefit. Suggestions for resolving conflicts of interest are predicated on the fact that, at a minimum, they must be resolved in compliance with the law and public policy. Individual physicians may, of course, choose the strictest personal moral course, e.g., totally avoiding potential conflicts by avoiding financial interests in the health care facilities or products or devices used in the provision of medical and health care services. Nevertheless, a middle ground is ethically permissible as long as the patient's welfare remains the priority. As professionals, physicians are committed to something more than personal gain. It has been well stated that:

> Historically, there are three ideas involved in a profession: organization, learning, i.e., pursuit of a learned art, and a spirit of public service. These are essential. A further idea, that of gaining a livelihood is involved in all callings. It is the main if not the only purpose in the...money-making callings. In a profession it is incidental. (R. Pound, THE LAWYER FROM ANTIQUITY TO MODERN TIMES, 1953, p.6).

In medicine, the tenet that financial interest should not interfere with the physician's medical judgments on behalf of the patient is ancient and is exemplified in Maimonides' Prayer (ca. 1190): "Do not allow thirst for profit, ambition for renown and admiration, to interfere with my profession for these are the enemies of truth and can lead me astray in the great task of attending to the welfare of Your creatures."

The public policy of entrepreneurialism has been suggested as a compelling impetus for each physician to examine any financial arrangement that may interfere or appear to interfere with the exercise of his best medical judgment on behalf of the patient. The Institute of Medicine has noted:

> All compensation systems - from fee-for-service to capitation or salary - present some undesirable incentives for providing too many services, or too few. No system will work without some degree of integrity, decency, and ethical commitment on the part of professionals. Inevitably, we must presume some underlying professionalism that will constrain the operation of unadulterated self-interest. The question is not to find a set of incentives that is beyond criticism, but to seek arrangements that encourage the physician to function as a professional, in the highest sense of that term. Certain changes that are occurring in our increasingly entrepreneurial health care system could undermine patients' trust in their physicians and society's trust in the medical profession. For those who believe that the professionalism of the physician is an essential element in ensuring the quality of health care and the responsiveness of institutions to the best interests of patients, an important question is whether that professionalism will be undermined by the increasingly entrepreneurial health care market in which physicians play a major part. (B.H. Gray, ed. FOR-PROFIT ENTERPRISE IN HEALTH CARE, 1986, p.153).

This report will identify situations that may give rise to conflicts of interest and provide suggestions for resolving them to the patient's benefit in conformity with the Council's guidelines, and in conformity with relevant public policies. Examples of conflicts of interest between the physician and the patient are provided (a) in the absence of third parties; and (b) in the presence of third parties.

SITUATIONS WITH THE POTENTIAL FOR CONFLICT OF INTEREST

Example 1: Physician dispenses drug or device to patient for profit.

Discussion: Unlike the situation where a physician prescribes a drug or device produced by a company in which he holds publicly traded stock whose profits and losses are determined by market forces, physician dispensing of drugs or devices and profiting directly thereby creates a conflict of interest if these are available through normal channels.

Public policies of several states prohibit physicians' dispensing where there is exploitation of the patient but permit it where there is disclosure and patient choice.[1]

Relevant opinions of the Council on Ethical and Judicial Affairs are:

Drugs and Devices: Prescribing. A physician should not be influenced in the prescribing of drugs, devices or appliances by a direct or indirect financial interest in a pharmaceutical firm or other supplier. Whether the firm is a manufacturer, distributor, wholesaler or repackager of the products involved is immaterial. Reputable firms rely on quality and efficacy to sell their products under competitive circumstances and do not appeal to physicians to have financial involvements with the firm in order to influence their prescribing.

Patients have an ethically and legally recognized right to prompt access to the information contained in their individual medical records. The prescription is an essential part of the patient's medical record. Physicians should not discourage patients from requesting a written prescription or urge them to fill prescriptions at an establishment which has a direct telephone line or which has entered into a business or other preferential arrangement with the physician with respect to the filling of the physician's prescription. (Section 8.06, CURRENT OPINIONS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, 1986)

Fee Splitting: Drug Prescription Rebates. A physician may not accept any kind of payment or compensation from a drug company for prescribing its products. The physician should keep the following considerations in mind: (1) A physician should only prescribe a drug based on his reasonable expectations of the effectiveness of the drug for the particular patient. (2) The quantity of the drug prescribed should be no greater than that which is reasonably required for the patient's condition. (Section 6.06, CURRENT OPINIONS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, 1986)

RF MENDATION I:

ALTHOUGH THERE ARE CIRCUMSTANCES IN WHICH PHYSICIANS MAY ETHICALLY ENGAGE IN THE DISPENSING OF DRUGS, DEVICES OR OTHER PRODUCTS, PHYSICIANS ARE URGED TO AVOID REGULAR DISPENSING AND RETAIL SALE OF DRUGS, DEVICES OR OTHER PRODUCTS WHEN THE NEEDS OF PATIENTS CAN BE MET ADEQUATELY BY LOCAL ETHICAL PHARMACIES OR SUPPLIERS.

Example 2: Physician refers patient to a facility or service owned by the physician in whole or in part.

Discussion: The Council's opinion on "Health Facility Ownership by Physician" (supra) applies. For example, the Council has stated that "A physician may own or operate a pharmacy if there is no resulting exploitation of patients." Under the Council's Conflict of Interest Guidelines, the physician-pharmacy owner would have to (1) disclose his ownership interest in the pharmacy; (2) prescribe only that quantity of a drug which is reasonably required for the patient's condition; (3) comply with all applicable laws, including those that restrict referrals to the physician's facility; (4) provide the patient with a written prescription so that the patient can have it filled wherever he wishes; and (5) make alternative arrangements for the care of the patient if the physician's commercial interest conflicts so greatly with the patient's interest as to be incompatible.

Public policies, as reflected in various statutes, range from the extremes of prohibiting referral to the physician's entity to no restrictions through the middle course of requiring disclosure of the ownership interest and patient choice.[2]

The ethical analysis requires an initial determination of what degree of financial interest creates a potential conflict with the patient's best interests. Where the physician's income is directly related to his ownership interest, there is a potential conflict. This conflict is most apparent where the physician is the sole owner of the entity to which he refers his patients. Failure to disclose an ownership interest which directly yields a financial benefit to the referring physician would be deceitful. Yet, it is in this situation that disclosure to the patient should be the easiest. A potential conflict of interest may also exist where the physician is a partial owner of the entity to which he refers his patients. In a situation where the physician is a partner or shareholder in the facility to which he refers his patient, the financial benefit to the referring physician may be so indirect and/or negligible as to create no conflict with his medical judgment. However, the appearance of impropriety for failing to disclose even a negligible financial benefit should be avoided by adherence to the Council's Conflict of Interest Guidelines. (See also Example 4 where physician's income is related to referrals to or from a third party.) The method of disclosing a physician's financial interest is that which makes it

known to the particular patient. As a practical matter, a written list of physician owners can be made available to the patient.

RECOMMENDATION: II

IN ACCORDANCE WITH THE COUNCIL'S CONFLICT OF INTEREST GUIDELINES, PHYSICIANS MAY REFER PATIENTS TO FACILITIES IN WHICH THEY HAVE AN OWNERSHIP INTEREST. HOWEVER, PHYSICIANS SHOULD SEEK TO AVOID EVEN THE APPEARANCE OF IMPROPRIETY IN MEDICAL DECISIONS THAT ARE EVEN REMOTELY RELATED TO THEIR FINANCIAL INTERESTS.

Example 3: Physician pays or is paid by third party for referral of patients.

Discussion: The classic example would be an instance where a physician refers a patient to another physician who remits a portion of the fee to the referring physician. Fee splitting has long been abhored by the medical profession. Referral on the basis of the physician's financial interest rather than confidence in the competence and ability to perform the services needed by the patient violates the physician's duty to deal honestly with patients and may result in the provision of unnecessary services.

It appears that most states have statutes making fee splitting or referral fees crimes or grounds for disciplinary action.[3] State statutes vary and their application to newly emerging business arrangements is problematical. For example, acceptance by a physician of an inducement to admit all of one's patients to the health facility of one offering the inducement might be construed as fee splitting.

The relevant opinions of the Council on Ethical and Judicial Affairs are:

> Fee Splitting. Payment by one physician to another solely for the referral of a patient is fee splitting and is improper both for the physician making the payment and the physician receiving the payment.
>
> A physician may not accept payment of any kind, in any form, from any source, such as a pharmaceutical company or pharmacist, an optical company or the manufacturer of medical appliances and devices, for prescribing or referring a patient to said source for the purchase of drugs, glasses or appliances.
>
> In each case, the payment violates the requirement to deal honestly with patients and colleagues. The patient relies upon the advice of the physician on matters of referral. All referrals and prescriptions must be based on the skill and quality of the physician to whom the patient has been referred or the quality and efficacy of the drug or product prescribed. (Section 6.04,

CURRENT OPINIONS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, 1986)

Fee Splitting: Clinic or Laboratory Referrals. Clinics or laboratories that compensate physicians based solely on the amount of work referred by the physician to the clinic or laboratory are engaged in fee splitting which is unethical. (Section 6.05, CURRENT OPINIONS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, 1986)

Nevertheless, the legitimate division of income among members of a group is sanctioned in the Council's opinion that:

Fees: Group Practice. The division of income among members of a group, practicing jointly or in a partnership, may be determined by the members of the group and may be based on the value of the professional medical services performed by the member and his other services and contributions to the group. (Section 6.03, CURRENT OPINIONS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, 1986)

RECOMMENDATION III:

REFERRALS SHOULD BE BASED UPON THE REFERRING PHYSICIAN'S CONFIDENCE IN THE COMPETENCE AND ABILITY OF THE INDIVIDUAL OR HEALTH CARE FACILITY'S ABILITY TO PERFORM THE SERVICES NEEDED BY THE PATIENT. WHEN SERVICES ARE PROVIDED BY MORE THAN ONE PHYSICIAN, EACH PHYSICIAN SHOULD SUBMIT HIS OWN BILL AND BE COMPENSATED SEPARATELY, IF POSSIBLE. IF THIS IS NOT POSSIBLE AND A FEE FOR SERVICES PERSONALLY RENDERED BY MORE THAN ONE PHYSICIAN IS TO BE DIVIDED, THE NATURE OF THE FINANCIAL ARRANGEMENT SHOULD BE MADE KNOWN TO THE PATIENT. PAYMENTS TO OR BY A PHYSICIAN FOR THE REFERRAL OF PATIENTS ARE IMPROPER. MERE REFERRAL DOES NOT CONSTITUTE A PROFESSIONAL SERVICE FOR WHICH A FEE MAY ETHICALLY BE CHARGED.

Example 4: Physician's income is related to referral of patients to or from a third party.

Discussion: Potential conflicts between the physician's own financial interest and his interest in the welfare of the patient can arise in every type of medical practice arrangement. In some instances a physician's income may be enhanced by increasing the number of referrals he makes to a third party. For example, a physician might be a partial owner of a health facility to which he refers patients. If a physician's income from his partial ownership of the health facility is based on a percent of the profits rather than a return on investment based upon capital contributions, there is the appearance of impropriety on the part of the referring physician. Similarly, a physician might lease equipment or space to another physician to whom he refers patients and receive a percentage of the

profits as rental. If the rental does not represent the fair market value of the use of equipment or space, there is an appearance of impropriety on the part of the referring physician as well as an issue of fee splitting with respect to the physician who pays an excessive rent.

The Council on Ethical and Judicial Affairs has previously stated its belief that physicians are not entitled to derive a profit that results from services provided by the hospital under DRG payments. Also, certain types of joint venture activities include "risk-sharing" or "incentive" features under which attending physicians whose care of patients results in hospital costs that fall short of the applicable DRG amount under the Medicare prospective payment system share in the "profits." In these arrangements, the hospital usually pays a percentage of its excess DRG payment to the attending physician directly or credits a like amount to a special account maintained on behalf of the physician group that is its partner in the joint venture. (See Judicial Council Report D, I-84, "Ethical Implications of Hospital-Physician Risk-Sharing Arrangements under Diagnosis-Related Groups System.")

In addition to possible violations of state fee splitting statutes, the Medicare and Medicaid antifraud and abuse statutes prohibit the knowing and willful solicitation, receipt, offer or payment of any remuneration in return for the party furnishing referrals. Remuneration includes kickbacks, bribes, and rebates given or accepted in cash or in kind, directly or indirectly, overtly or covertly. The statutory language indicates Congress's intent to include practices that the federal government believed were causing unnecessary utilization and costing billions of dollars for unnecessary services and fraudulent claims.

A number of decisions indicate that the U.S. Department of Health and Human Services (HHS) and the courts interpret these statutes broadly. The most recent decision, United States v. Greber, 760 F.2d 68 (3d Cir. 1985), concerned a cardiologist whose company, Cardio-Med, Inc., provided physicians with diagnostic services. At issue in this case was the Holter-monitor service provided. Cardio-Med billed Medicare for the monitor service and forwarded a portion (40 percent but not to exceed $65.00 per patient) of the payment received to the referring physician. The fees were described as payment for the referring physician to explain the results to the patients. There was evidence that the referring physicians received their payments even though the cardiologist actually evaluated the Holter-monitor results. The court found that, according to the language and purpose of the statute, if the payments to the referring physicians were intended to induce those physicians to use Cardio-Med's services, the statute was violated, even if the payments were also intended to compensate for professional services.

RECOMMENDATION IV:

WHERE A PHYSICIAN'S INCOME MAY BE ENHANCED BY REFERRALS TO AN ENTITY IN WHICH HE HAS AN OWNERSHIP INTEREST, INCOME GENERATION SHOULD BE SEPARATE FROM VOLUME OF REFERRALS OR UTILIZATION. ALTERNATIVES MIGHT INCLUDE CORPORATE STRUCTURES WHERE: (1) RETURN ON EQUITY IS A FIXED OR INDEPENDENTLY DETERMINED RATIO REFLECTING CAPITALIZATION RATHER THAN INDIVIDUAL PROFESSIONAL REFERRALS; (2) MANAGEMENT AND PROFESSIONAL ENTITIES ARE SEPARATE; AND/OR (3) THERE IS INDEPENDENT UTILIZATION REVIEW, CONCURRENTLY OR RETROSPECTIVELY. SUCH MECHANISMS MIGHT HELP TO ASSURE (1) THAT INCOME IS NOT RELATED TO THE NUMBER OF REFERRALS OR THE REVENUE GENERATED BY THE PHYSICIAN OWNER OR INVESTOR BUT, INSTEAD, TO OWNERSHIP AND EQUITY CONSIDERATIONS; (2) THAT REFERRALS ARE MADE FOR MEDICALLY NECESSARY SERVICES; AND (3) THAT CHARGES ARE NOT EXCESSIVE.

On the other hand, a physician's income may be enhanced by decreasing the number of referrals he makes. For example, a physician might serve as a primary care case manager who is responsible for coordinating and controlling access to other health services needed by the patient. The primary care case manager is often placed at financial risk for the cost of care he orders. As noted by the Council on Medical Service in its report on "The Concept of a 'Gatekeeper'" that was adopted by the House of Delegates at its 1986 Annual Meeting, "...the physician providing 'gatekeeper' or primary care case management services is entitled to charge an appropriate fee for such services." (Council on Medical Service Rep. 4, A-86).

The Council on Medical Service noted the following potential advantages unique to the "gatekeeper" approach: (1) stronger incentives toward prudent use of resources; and (2) the elimination of duplicative services. The Council also noted the following potential disadvantages unique to the "gatekeeper" approach: (1) an incentive to underserve patients; (2) possible delays in obtaining needed secondary or tertiary services; and (3) the provision of such services by less qualified practitioners, as well as restrictions on the patient's freedom of choice of the specialized provider.

The American Medical Association is committed to free market competition among various health care delivery systems, with the growth of each determined by the number of persons who prefer that mode of delivery.

The Council on Ethical and Judicial Affairs has stated:

Contractual Relstionships. The contractual relationships that physicians assume when they enter prepaid group practice plans are varied.

Income arrangements may include hourly wages for physicians working part time, annual salaries for those working full time, and shsre of group income for physicians who are partners in groups that are somewhst sutonomous and contract with plans to provide the required medical care. Arrangements also usually include s range of fringe benefits, such as paid vacations, insurance and pansion plans.

Physicians may work directly for plans or may be employed by the medical group or the hospital that has contracted with the plan to provide services. The AMA recognizes that under proper legal authority such plans may be established and that a physician may be employed by, or otherwise serve, a medical care plan. In the operation of such plans, physicians should not be subjected to lay interference in professional medical matters and their primary responsibility should be to the patients they serve. (Section 8.05, CURRENT OPINIONS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, 1986)

Referral of Patients-Disclosure of Limitations. When a physician agrees to provide treatment, he thereby enters into a contractual relationship and assumes an ethical obligation to treat the patient to the best of his ability. PPO and HMO contracts generally restrict the participating physician's scope of referral to medical specialists, diagnostic laboratories, and hospitals that have contractual arrangements with the PPO or HMO. Some plans also restrict the circumstances under which referrals may be made to contracting medical specialists. If the PPO or HMO does not permit referral to a noncontracting medical specialist or to a diagnostic or treatment facility when the physician believes that the patient's condition requires such services, the physician should so inform the patient so that the patient may decide whether to accept the outside referral at his own expense or confine himself to services available within the PPO or HMO. In determining whether treatment or diagnosis requires referral to outside specialty services, the physician should be guided by standards of good medical practice. (Section 8.12, CURRENT OPINIONS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, 1986)

RECOMMENDATION V:

IT IS UNETHICAL TO INTENTIONALLY LIMIT UTILIZATION OF NEEDED MEDICAL SERVICES TO THE DETRIMENT OF A PATIENT FOR THE PHYSICIAN'S OWN PROFIT. IF A THIRD PARTY LIMITS A PATIENT'S ACCESS TO NECESSARY MEDICAL SERVICES CONTRARY TO STANDARD MEDICAL PRACTICE, THE PHYSICIAN SHOULD SO INFORM THE PATIENT AND PROTEST THE LIMITATION.

- CONCLUSION -

Financial rewards to physicians for the referral of patients or for failing to refer patients for necessary medical services can have, at least, the appearance of impropriety and can undermine the public's confidence in the medical profession. Medical decisions made solely on the basis of financially benefiting the physician are improper. The overriding principle is that conflicts between the physician's financial interest and the patient's medical interest must always be resolved to the benefit of the patient. Where the conflict is so great that the patient's interest is not served, the physician must cede the care of the patient to another qualified physician.

The trust and dependence reposited in the physician by the patient invokes an ethical obligation on the part of the physician far greater than that of the commercial purveyor of services. The obligation of the physician is to be an advocate for the patient. A physician must exercise medical judgment independently of his own or a third party's financial interests. No motive should be allowed to prevail against the physician's fundamental role of alleviating the suffering of his patients. If a third party attempts to corrupt the physician's exercise of medical judgment on behalf of his patients, the physician must be the advocate of the patient and vigorously oppose those who are adverse to the medical interests of the patient. If the physician's own interests are adverse to the patient's interests, alternative arrangements must be made for the care of the patient. The physician must never assume a position adverse to the interests of the patient.

The Council on Ethical and Judicial Affairs recommends that this report be filed.

77-496 0 - 87 - 2

APPENDIX

The following references to selected state statutes and opinions of state attorneys general are provided as illustrations of various public policy approaches. This is not intended as a comprehensive review of the law on these subjects. It is recommended that the current law of the jurisdiction be consulted.

[1]Florida statutes provide that the following are grounds for disciplinary action:

> "Exercising influence on the patient or client in such a manner as to exploit the patient or client for financial gain of the [physician] or of a third party which shall include, but not be limited to, the promoting or selling of services, goods, appliances, or drugs and the promoting or advertising on any prescription form of a community pharmacy unless the form shall also state 'this prescription may be filled at any pharmacy of your choice'." FLA. STAT. ANN. §458.331(1)(o) (West 1981).

An Illinois statute provides that the "Promotion of the sale of drugs, devices, appliances or goods provided for a patient in such manner as to exploit the patient for financial gain of the physician" is a basis for disciplinary action. ILL. STAT. ANN. Ch.111, §4433 (18) (Smith-Hurd 1986).

A Missouri attorney general's opinion indicates that "A physician who requires that his patient accept drugs dispensed by the physician and refuses to provide the patient a prescription for such drugs which can be filled at a pharmacy of the patient's choice may be in violation of the Missouri Antitrust Law and [the section stating grounds for denial, revocation or suspension of physicians' licenses]." Op. Att'y. Gen. No. 6, (July 8, 1982).

Rhode Island defines "unprofessional conduct" to include "promotion by a physician...of the sale of drugs, devices, appliances, or goods or services provided for a patient in such manner as to exploit the patient for the financial gain of the physician." R.I. GEN. LAWS §5-37.1-5(6) (1985).

A Texas statute provides that a licensed physician "is authorized to supply the needs of his patients with any drugs or remedies as are necessary to meet the patients' immediate needs" but a physician is not permitted "to operate a retail pharmacy without first complying with the Texas Pharmacy Act." An exception is permitted for "A licensed physician who practices medicine in a rural area in which there is no pharmacy" to "maintain a supply of dangerous drugs..." TEX. STAT. ANN. art. 4495(b) §5.09 (Vernon 1986).

A Virginia statute provides that the following constitutes unprofessional conduct:

> Being a practitioner of the healing arts who may lawfully dispense, administer, or prescribe, medicines or drugs, and not being the holder of a certificate of registration to practice pharmacy, engages in selling medicine, drugs, eyeglasses, or medical appliances or devices to persons who are not his own patients, or sells such articles to his own patients either for his own convenience, or for the purpose of supplementing his income; provided, however, that the dispensing of contact lenses by a practitioner to his patients shall not be deemed to be for the practitioner's own convenience or for the purpose of supplementing his income. VA. CODE §54-317(12) (1985).

In addition, the Virginia State Board of Medicine "shall have authority to promulgate rules and regulations regulating the sale of vitamins or food supplements by any practitioner of the healing arts from the office in which he practices." VA. CODE §54-278.2 (1985).

[2]California provides a detailed statutory scheme of regulation. Section 650 of the California Business and Professions Code provides that:

> Except as provided [in the sections of the Health and Safety Code relating to referral agencies] and in Section 654.1 it shall not be unlawful for any person licensed under this division to refer a person to any laboratory, pharmacy, clinic, or health care facility solely because such licensee has a proprietary interest or co-ownership in such laboratory, pharmacy, clinic, or health care facility; but such referral shall be unlawful if the prosecutor proves that there was no valid medical need for such referral."

It is the California attorney general's opinion that physicians may refer patients to clinical laboratories in which they have limited partnership interests without violating the prohibition on rebates and kickbacks if the physician informs patients (in writing) of that interest and that they are free to choose another laboratory to have the work performed. There is a valid medical need for the referral, and the physician's return on his or her investment is not measured by the number or value of his or her referrals. Op. Att'y. Gen. No. 84-806 (Feb. 8, 1985). Another California attorney general's opinion states that the provision of "professional courtesy services" by clinical laboratories to a physician or his family or to his physician-patients or their families violates this section only where such services are provided as compensation or inducement for referring patients to the clinical laboratory. Ops. Att'y. Gen. No. 79-920 (Feb. 8, 1980).

Section 654.? of the California Business and Professions Code makes it unlawful for a physician:

CEJA Rep. A - page 14

(a)...to charge, bill, or otherwise solicit payment from a patient on behalf of, or refer a patient to, an organization in which the licensee, or the licensee's immediate family, has a significant beneficial interest, unless the licensee first discloses in writing to the patient that there is such an interest and advises the patient that...the patient may choose any organization for the purpose of obtaining the services ordered or requested by the [phyaician].

(b) The disclosure requirements of subdivision (a) may be met by posting a conspicuous sign in an area which is likely to be seen by all patients who use the facility or by providing those patients with a written disclosure statement. Where referrals, billings, or other solicitations are between licensees who contract with multispecialty clinics pursuant to subdivision (1) of Section 1206 of the Health and Safety Code or who conduct their practice as members of the same professional corporation or partnership, and the services are rendered on the same physical premises, or under the same professional corporation or partnership name, the requirements of subdivision (a) may be met by posting a conspicuous disclosure statement at a single location which is a common area or registration area or by providing those patients with a written disclosure statement...

(c) For the purposes of this section, the following terms have the following meanings:

(1) "Immediate family" includes the spouse and children of the licensee, the parents of the licensee and licensee's spouse, and the spouses of the children of the licensee.

(2) "Significant beneficial interest" means any financial interest that is equal to or greater than the lesser of the following:

(A) Five percent of the whole.

(B) Five thousand dollars ($5,000).

(d) This section shall not apply to a "significant beneficial interest" which is limited to ownership of a building where the space is leased to the organization at the prevailing rate under a straight lease agreement or to any interest held in publicly traded stocks.

(e)(1) This section does not prohibit the acceptance of evaluation specimens for proficiency testing or referral of specimens or assignment from one clinical laboratory to another clinical laboratory, either licensed or exempt under this chapter, if the report indicates clearly the name of the laboratory performing the test.

The statute does not apply if the physician, organization, or entity is providing or arranging for health care services pursuant to a prepaid capitated contract with the California State Department of Health Services.

However, Section 650.1 provides that:

> "any amount payable to...any person [licensed under the medical practice act] or corporation prohibited from pharmacy permit ownership...under any rental lease or service arrangement with respect to the furnishing or supply of pharmaceutical services and products, which is determined as a percentage, fraction, or portion of (1) the charges to patients or of (2) any measure of...pharmacy revenue or cost, for pharmaceuticals and pharmaceutical services is prohibited.

Section 654 provides that licensed physicians "may not have any membership, proprietary interest or ownership in any form in or with any person licensed [as an optician] to whom patients, clients or customers are referred or any profit-sharing interests."

Section 654.1 provides that licensed physicians "may not refer patients, clients, or customers to any clinical laboratory in...which the licensee has any membership, proprietary interest, or co-ownership in any form, or has any profit-sharing arrangement, unless the licensee at the time of making such referral discloses in writing such interest to the patient, client, or customer. The written disclosure shall indicate that the patient may choose any clinical laboratory for purposes of having any laboratory work or assignment performed." This section does not apply (1) to persons who are members of a medical group which contracts to provide medical care to members of a group practice prepayment plan registered under the Knox-Keene Health Care Service Act of 1975; (2) to any referral to a clinical laboratory which is owned and operated by a licensed health facility and (3) to the acceptance of evaluation specimens for proficiency testing or referral of specimens or such assignment from one clinical laboratory to another if the report indicates clearly the laboratory performing the test. Also, "proprietary interest" does not include ownership of a building where space is leased to a clinical laboratory at the prevailing rate under a straight lease arrangement.

Florida provides that the following is a ground for disciplinary action and a misdemeanor punishable by a year in prison and/or a $1,000 fine for osteopathic physicians:

> Referring any patient, for health care goods or services, to any partnership, firm, corporation, or other business entity in which the physician or the physician's employer has an equity interest of 10 percent or more, unless prior to such referral, the physician notifies the patient of his financial interest and of

the patient's right to obtain such goods or services at the location of the patient's choice. This section shall not apply to the following types of equity interests.

1. The ownership of registered securities issued by a publicly held corporation or the ownership of securities issued by a publicly held corporation, the shares of which are traded on a national exchange or the over the counter market;

2. A physician's own practice, whether the physician is a sole practitioner or part of a group, when the health care good or service is prescribed or provided solely for the physician's own patients and is provided or performed by the physician or under the physician's supervision; or

3. An interest in real property resulting in a landlord-tenant relationship between the physician and the entity in which the equity interest is held, unless the rent is determined, in whole or in part, by the business volume or profitability of the tenant, or is otherwise unrelated to fair market value. 1986 FL. SESS. LAW SERV. 86-290 (West). (to be codified at FL. STAT. §459.013 (3)(b)).

Also, "It shall be a misdemeanor of the first degree...for any health care practitioner...[to] provide medicinal drugs from any source other than on a complimentary basis when the practitioner has a financial interest or for which the practitioner will receive some financial remuneration, unless in advance of any such referral, the practitioner notifies the patient, in writing, of such financial interest." 986 FL. SESS. LAW SERV. 86-31 (West) (to be codified at FL. ST .. §455.25).

A Michigan statute defines as unprofessional conduct: "Promotion for personal gain of an unnecessary drug, device, treatment, procedure, or service, or directing or requiring an individual to purchase or secure a drug, device, treatment, procedure, or service from another person, place, facility or business in which the licensee has a financial interest." MICH. STAT. ANN. §14.15 (16221)(e)(iii). A Michigan attorney general's opinion provides that violation of the prohibition against a licensed health professional having a financial interest in a clinical laboratory is not avoided by disclosure of the interest to the individual being directed or required to obtain a drug, device, treatment, procedure or service. Op. Att'y. Gen. No. 5498 (June 8, 1979). Further, the opinion provides that:

A licensed health professional is prohibited from directing or requiring an individual to purchase or secure a drug, device, treatment, procedure or service, even if necessary, from a person, place, facility or business in which the licensed health professional has a financial interest. A licensed health

professional has a "financial interest" in a clinical laboratory if he or she is the proprietor, a partner, a limited partner, a shareholder. or has a similar business interest in the clinical laboratory. Ibid.

A Missouri Attorney General's opinion states that:

"A physician who instructs or requires a patient to use a pharmacy in which the physician has a financial interest to fill a drug prescription may be in violation of the Missouri Antitrust Law and this section listing grounds for denial, revocation or suspension of physician's licenses. Op. Att'y. Gen. No. 6 (1982).

[3]Section 650 of the California Business and Professions Code provides:

Except as provided...[with respect to licensed referral agencies,] the offer, delivery, receipt or acceptance, by any person licensed under this division of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to any person, irrespective of any membership, proprietary interest or co-ownership in or with any person to whom such patients, clients or customers are referred unlawful...

An Illinois statute provides the following as grounds for disciplinary action: "Directly or indirectly giving to or receiving from any physician, person, firm or corporation any fee, commission, rebate or other form of compensation for any professional services not actually and personnally rendered." However, this does not prohibit licensed physicians from practicing medicine in partnership under a partnership agreement or in an authorized corporation, professional association, or professional corporation, "or from pooling, sharing, dividing or apportioning the fees and monies received by them or by the partnership, corporation or association in accordance with the partnership agreement or the policies of the Board of Directors of the corporation or association." Nor does the statute prohibit two or more authorized corporations from "forming a partnership or joint venture of such corporations, and providing medical, surgical and scientific research and knowledge by employees of these corporations if such employees are licensed under this Act, or from pooling, sharing, dividing, or apportioning the fees and monies received by the partnership or joint venture in accordance with the partnership or joint venture agreement." Nor does the statute "abrogate the right of two or more persons holding valid and current licenses under this Act to receive adequate compensation for concurrently rendering professional services to a patient and divide a fee; provided, the patient has full knowledge of the division, and, provided, that the division is made in proportion to the services performed and

responsibility assumed by each. ILL. ANN. STAT. Ch.111, §4433(14) (Smith-Hurd 1986).

And again the Illinois statute defines as unprofessional conduct: "Solicitation of professional patronage by any corporation, agents or persons, or profiting from those representing themselves to be agents of the licensee." ILL. ANN. STAT. Ch.111, §4433(23) (Smith-Hurd 1986).

Rhode Island defines the following as "unprofessional conduct:" 1956 R.I. GEN. LAWS §5-37.1-5(11) and (12) (1985).

- Solicitation of professional patronage by agents or persons or profiting from acts of those representing themselves to be agents of the licensed physician or limited registrants;

- Division of fees or agreeing to split or divide the fees received for professional services for any person for bringing to or referring a patient.

A Texas statute provides:

> A physician or surgeon may not employ or agree to employ, pay or promise to pay, or reward or promise to reward any person, firm, association of persons, partnership, or corporation for securing, soliciting, or drumming patients or patronage. A physician or surgeon may not accept or agree to accept any payment, fee, reward, or anything of value for securing, soliciting, or drumming for patients or patronage for any physician or surgeon...The preceding shall not be construed to prohibit advertising except that which is false, misleading, or deceptive or that which advertises professional superiority or the performance of professional service in a superior manner and that is not readily subject to verification. TEX. STAT. ANN. art 4495b Sec. 3.07(c) (Vernon 1986).

Mr. WAXMAN. Thank you very much for your testimony. We are being summoned to the House Floor to respond to a vote. Before we ask either of you questions, we will take a recess. We hope it will be no more than 10 minutes.

Mr. LELAND. Mr. Chairman, will you recognize me for an unanimous consent request?

Mr. WAXMAN. The gentleman is recognized for that purpose.

Mr. LELAND. Mr. Chairman, I ask unanimous consent that my opening statement be entered into the record.

Mr. WAXMAN. Without objection, your opening statement will be entered into the record.

[The prepared statement of Hon. Mickey Leland follows:]

STATEMENT OF HON. MICKEY LELAND

Mr. Chairman, I want to congratulate you for your insightful leadership on the issue of physician dispensing of drugs. There are a number of problems associated with this practice including the elimination of a key member of the health care team, that is, the pharmacist. I support Congressman Wyden's bill, H.R. 2093, as an important step in guarding the health of our citizens and retaining the integrity of the checks and balances designed to insure appropriate drug therapy. Our failure to maintain this integrity would be a grave error.

Mr. Chairman, the concept of physicians dispensing pharmaceuticals to their patients is not new. However, we have recently seen an explosion of this practice as more and more physicians become sold on the idea of selling pharmaceuticals to their patients to enhance the profitability of their practices. Such a practice invites abuse and can lead to great difficulty in monitoring overall drug therapy for patients.

Physicians are trained as diagnosticians and clinicians. Typically, they have one semester of pharmacology and possibly a 6 week course in therapeutics. Physicians have NO training in the dispensing of pharmaceuticals. The pharmacist, on the other hand, is trained specifically and is uniquely qualified to dispense drugs.

Mr. Chairman, as a former Clinical Pharmacy Instructor at Texas Southern University, I know the rigorous training pharmacy students receive in every aspect of drug therapy. A large portion of a pharmacist's education is devoted to such courses as Pharmaceutics, Pharmacology, clinical Pharmacology, Therapeutics, and Physical Pharmacy. In other courses, including formulation and compounding courses, students learn not just the differences between pills and tablets, but the myriad of dosage forms, composition, characteristics, and storage requirements. Pharmacy students also learn about critical considerations as a patient's age, physical condition, and the integration of therapy with daily schedules.

H.R. 2093 would allow traditional physician dispensing functions to continue. The historically strong working relationship between physicians and pharmacists would be preserved. Such activities as sample distribution and emergency dispensing of limited quantities would not be affected. H.R. 2093 gives needed protection to the public while retaining the integrity of medical practice.

Again, thank you for the opportunity to express my support for this bill and I commend you on your efforts to eliminate the actual and potential public health problems posed by physician dispensing of drugs.

Mr. WAXMAN. We will now recess just as long as it will take to respond to the vote and then we will return so we can ask questions of these two witnesses.

[Brief recess.]

Mr. WAXMAN. Dr. Dickey, let me see if I understand the AMA's position on this question. As I understand your testimony, the American Medical Association believes it would be unethical for a doctor to prescribe medications and make a profit from dispensing the prescription. Is that a fair statement?

Ms. DICKEY. No. I think perhaps our position is a little more limited than that. We have advised physicians who choose to regularly dispense medications that there are some guidelines which they

should follow. For example, they should be sure to notify the patient that they are dispensing for a profit. They should be sure that the patient is informed if there are other sources available, other pharmacies in town or at whatever place available, and be sure that the patient understands they have a free choice of where they choose to get their prescription filled.

If they have done that full disclosure, then we feel that the physician has met the ethical guidelines to avoid the conflict of interest that is inherent in such a situation.

Mr. WAXMAN. So there is a conflict of interest inherent in the situation and what is required of a physician under the ethics of the American Medical Association is that that inherent conflict be disclosed?

Ms. DICKEY. Exactly.

Mr. WAXMAN. As I understand the report of the AMA's Council on Ethical and Judicial Affairs, that was appended to your testimony, it states that with regard to drug prescription rebates, a physician may not accept any kind of payment or compensation from a drug company for prescribing its products.

Is there any real difference between rebates and profit margins? If physicians are made acutely aware of potentially higher profit from dispensing one drug instead of another or instead of the identical product from another manufacturer, wouldn't this operate in much the same way as a rebate?

Ms. DICKEY. The rebates that are discussed in terms of that are in the form of a kick back or a fee splitting in order to encourage a physician to prescribe one product over another. I think that in the same method a pharmacy can choose to pass on all or part of a wholesale cost difference, probably a physician could make the same choice.

Mr. WAXMAN. The physician is making a choice to prescribe one drug as opposed to another drug. If they stand to make a profit by prescribing drug X instead of drug Y, aren't they in the same position that they would be in if they prescribed drug X and they made a profit because the drug company sent them a check as opposed to knowing they are going to get an extra check for making that prescription of that particular drug?

Isn't it the same thing? Isn't the physician being influenced by something other than the best interest of the patient?

Ms. DICKEY. The potential exists and that's the reason for the conflict of interest type of guidelines in terms of full disclosure. The difference is that if I choose to take a rebate check from a pharmacy, then the likelihood is not that I am going to sit down with my patient as I hand him his prescription to go to the local pharmacy and tell them, by the way, I prescribed a particular brand of penicillin because I'm going to get a check in the mail at the end of the month.

On the other hand, if I do disclose to the patient that I have just given him a prescription for medication, he can choose to fill that in my office where he may pay a premium price because of convenience or he can choose to go down the street and fill it at the local pharmacy, that disclosure allows the patient to make the choice.

Mr. WAXMAN. But the disclosure will be, I, Dr. Waxman, am giving you a prescription which I'd be happy to fill for you at a

price, which would include a profit for me. I want you to know I'm going to make a profit, and by the way, you can go down to a pharmacy and get this filled as well, if you so choose.

That patient is not going to know if I made the choice for that particular drug based on the knowledge that I have, or on the particular drug I have in my office that I can sell to that patient. But there may be another drug that may be cheaper and there may be another drug that may be slightly better for that patient. That is something that can't really be disclosed because it's something called human nature, that even physicians suffer from.

Ms. DICKEY. I understand; occasionally.

Mr. WAXMAN. Your position would be if we saw this to be a problem, the States should move and not the Federal Government?

Ms. DICKEY. Absolutely.

Mr. WAXMAN. You are not asking the States to adopt legislation but you are saying if anyone were to adopt legislation, it ought to be the States?

Ms. DICKEY. If the States have identified that they have a problem with this, then we feel that the State should be the proper place for any regulations or statutes to be written. That's the level at which the physicians and pharmacists are licensed. That's the level at which the disciplinary boards function and can utilize our ethical guidelines among others with which to discipline physicians.

Mr. WAXMAN. Human nature is interesting and we see it all the time in a lot of areas legislatively, and in health care, we see it as well. The cost of health care has been going up dramatically. On the hospital side, we used to reimburse hospitals for whatever their costs were and then we decided that is crazy because their costs kept on going up and up and up because they got reimbursed whatever their costs were. We said, we are going to change the system.

We reimburse doctors on a fee for service basis. Doctors found in many cases that the more services they performed, the more money they made.

I can understand that. I just think ethical people who want to do the right thing may see things a little differently because they stand to gain by it. I'm just wondering if we are not asking for trouble here and maybe we ought to talk about legislation before we get into an issue where we have a whole vested interest of doctors that stand to lose money because we are going to take away a new practice, a new business from them that many of them may start getting into in a major way.

I raise that as a more rhetorical question. But, I think it goes to the very heart of this issue. Should we leave the decisions that affect the quality of health care to people who have a conflict of interest and only rely on them to recognize the conflict and to disclose it as the solution? My time is up and I want to recognize other members of the subcommittee.

Let me turn to Mr. Wyden next and recognize him for some questions.

Mr. WYDEN. Mr. Oliver, if I might, you said that the FTC was not hampering any State efforts to regulate physician sales. Yet in a letter to the Georgia Board of Pharmacy, Jeffrey Zuckerman, who heads the Bureau of Competition for the FTC said that limitations

on physician sales would impose discriminatory constraints on practitioners. He went on to say that it could violate anti-trust laws.

It seems to me that is a stiff warning to the States that they should not be involved in any efforts to limit physician sales.

What is your response to this?

Mr. OLIVER. Mr. Wyden, I apologize for not introducing earlier the man at my left, who is the Director of the Bureau of Competition and the author of the letter you mentioned, Mr. Jeffrey Zuckerman. I suggest the best way to answer the question is to ask Mr. Zuckerman to answer it.

Mr. WAXMAN. Could we for the record indicate that he is to your right, our left.

Mr. OLIVER. I'm sorry. There are very few people over there.

Mr. WYDEN. This is just a good moment, I'm not going to repeat my question.

Mr ZUCKERMAN. If I may, I would just like to note two things about the Georgia situation. What the Georgia Board was proposing there was a twofold type of regulation. One part of their proposed regulations required dispensing physicians to comply with the same regulations as pharmacists. We, the staff of the Federal Trade Commission, expressed no objection whatsoever to such equal playing field type regulations.

On the other hand, the Georgia Board was also proposing to impose additional restrictions on dispensing physicians beyond those that were imposed upon pharmacists, and those we pointed out would restrict the choices of consumers, and thus reduce competition to the detriment of the consumers, the patients of the doctors and the customers of the pharmacists.

We also noted that in that instance, there were serious questions about whether that Board was in fact acting consistent with what we call the State Action Doctrine. Was it acting pursuant to a clearly articulated State policy? Was it actively supervised by the State or was it in fact simply a private group of pharmacists adopting a set of restraints on competition which would violate the antitrust laws?

Mr. WYDEN. Mr. Zuck· man, it seems clear to me that the net impact of what you ha· ·ten to the Georgia Board of Pharmacy, State legislative b regulatory bodies, is actively to discourage them from p· nitations on physician sales. Is that correct?

Mr. ZUCKERMAN. What .e were hoping to do was to bring to their attention the injury to consumers that would result by their placing restrictions on physicians that they did not place on pharmacists and naturally, we would hope that when they realized they would be injuring those consumers, that as a result of realizing that, they would not take the proposed action.

Mr. WYDEN. Do you have any empirical evidence of this injury to consumers that you feel would result if the States were to limit p· ·sician sales? Have you done any empirical analysis?

Mr. ZUCKERMAN. I would submit that in light of the fact that physician dispensing is a long established decades old practice, it would seem to me and it is the position of the staff of the Commission at least, that those who would restrict the choice of consum-

ers, those that would restrict competition, should have the burden of coming forward and showing the problems, the serious and immediate threat to the public health and safety to justify restraining competition, to justify restricting consumer choice.

Mr. WYDEN. First of all, while this may have gone on for years, it has only become a major industry recently. That is why I read what Stock Market Magazine projects. Stock Market Magazine now projects in an interview with James Roberts, one of the leaders in this field, that it is going to be a $20.3 billion industry. We do not dispute the fact that there were in emergency situations, in rural areas, physician sales going on, but this is brand new. There are large quantities of money to be made in sales and this is not decades old.

I also note that your predecessors at the Federal Trade Commission, specifically Chairman Caspar Weinberger, was concerned years ago about physician sales. In fact, the Nixon White House, the Justice Department and the FTC all testified in the 1970's against physician sales. So what we are talking about here is an administration reversing policy, reversing government policy.

You are specifically endorsing this practice and discouraging State attempts to try and put restrictions on sales.

My time has expired but I will have some more questions in a moment, Mr. Chairman.

Mr. WAXMAN. We will have another round. Mr. Fields.

Mr. FIELDS. Thank you, Mr. Chairman.

Dr. Dickey, it seems that some of these questions that are being raised may be legitimate but I guess my basic question is: shouldn't these questions be raised at the State level? It's my understanding that in Texas we have a statute that provides that a licensed physician is authorized to supply the needs of his patients with any drugs or remedies as are necessary to meet the patients' immediate needs; that a physician is not permitted to operate a retail pharmacy without first complying with the Texas Pharmacy Act. An exception is permitted for a licensed physician who practices medicine in a rural area in which there is no pharmacy to maintain a supply of dangerous drugs.

What have been the practical applications of that statute in Texas?

Ms. DICKEY. To the best of my knowledge, it has worked well. There have not been widespread problems with the Texas statute. Indeed, we have a number of rural areas. They use the statute as necessary to deal with specific problems. I think that is one exam ple where a State has looked at its individual problems and has written a statute that has appropriately addressed those.

Mr. FIELDS. To your knowledge, are we discouraged from doing this by the FTC or any other Federal entity?

Ms. DICKEY. No, sir.

Mr. FIELDS. I guess the question that comes to my mind, if we did it in Texas and it seems to be working, and it seems this is an issue of State province, why is this particular committee going forward? That is something that you really can't answer. Thank you.

Ms. DICKEY. Of course. Thank you.

Mr. WAXMAN. Has the gentleman completed his questions and yielded back the balance of his time?

Mr. FIELDS. Yes.

Mr. WAXMAN. Mr. Dowdy.

Mr. DOWDY. Thank you, Mr. Chairman.

In the testimony of one of the witnesses, you state that the practice of physician dispensing is increasing and you point out that further growth is projected particularly at non-traditional types of health care facilities. I don't remember which of you were talking about that.

If this were to become Federal legislation, what impact would it have on the non-traditional types of health care facilities? I suppose we are talking about HMO's. Would it have a retarding effect on those types of practices?

Mr. OLIVER. Depending on the structure of the particular non-traditional type of practice and also depending upon the final wording of the language, it might very well make dispensing drugs by physicians either more difficult or impossible or if it made it more difficult, it would tend to raise the costs.

The point about physician dispensing is that it may provide either convenience, let us say, or a lower cost to the patient and any restrictions we put on physician dispensing would tend to take away whatever cost benefit the patient might be able to obtain.

Mr. DOWDY. Maybe I should be asking Mr. Wyden this. Is there an exception, as the legislation is now drawn up, whereby he accepts the non-traditional medical practice vehicle such as the HMO's?

Mr. WYDEN. Would the gentleman yield on that?

Mr. DOWDY. Yes.

Mr. WYDEN. Yes. The Group Health Association has recommended some very technical changes in the bill. It has offered its endorsement with those and they are fine with me. We are not interested in doing damage to the groups the gentleman is talking about. We will make the technical changes that the Group Health Association has asked for and we appreciate their support.

Mr. DOWDY. I direct this question to either of the witnesses. Under FTC regulation at this time, what is there now to protect a patient from the wrongs that Mr. Wyden is talking about? For example, in the AMA's testimony, Doctor, you say for example, "Physicians could be encouraged or even required by States to inform their patients that they have the right to have their prescriptions filled wherever they choose and after such full disclosure . . ." what is either in Federal legislation or FTC regulations now that gives patients this protection? Is there anything now?

Mr. OLIVER. Not to my knowledge, Mr. Dowdy, nor to my knowledge is there any requirement that a physician advise his patient that he doesn't have to have his xray in the office or doesn't have to use the blood laboratory in his office. That is left essentially to the patient's discretion and to competition to allow the patient to determine whatever may make more sense.

Mr. DOWDY. Doctor.

Ms. DICKEY. There is not legislation to that effect, Representative Dowdy, but there are ethical guidelines which are promulgated and accepted by all of the State medical associations and used to measure the conduct of physicians. Those are very explicit, as I explained earlier, in terms of full disclosure and being sure that pa-

tients are aware that they have the right of choice, whether you are talking about dispensing of drugs or getting laboratory and xray tests done. Medical associations and societies not only make sure those are widely known amongst physicians but use those for disciplining physicians when appropriate.

I think it is important to note, too, that we still haven't seen demonstration of a significant number of episodes where there is a problem demonstrated of price gauging and restricting of patients in where they can fill their prescriptions and so forth.

Mr. DOWDY. One other question and then I want to yield to Mr. Wyden. If this hearing today reveals that there are no widespread episodes, what would be your reaction to legislation that goes not as far as Mr. Wyden's proposed legislation but would put in the Federal law a requirement that patients be informed of their physicians' involvement?

Ms DICKEY. We are in favor of informing the patients and being sure they know their choices available. We continue to feel that this is an issue that should be dealt with at the State level and not through Federal legislation

Mr. WAXMAN. The gentleman's time has expired.

Mr. Bliley. Mr. Bates. Mr. Walgren.

Mr. WALGREN. Thank you, Mr. Chairman.

Chairman Oliver, I gather you do not support the position the AMA took here that physicians should avoid the regular dispensing of drugs.

Mr. OLIVER. I think that the physician should make up his own mind, essentially. If the consumers, his patients want him to dispense drugs, I think that is a decision for the physician.

Mr. WALGREN. And your own involvement through the FTC, I gather, would not really focus on the kinds of questions that the physicians focused on in taking a position on whether or not they should regularly dispense drugs. I gather those are areas of concern that are not really yours.

Mr. OLIVER. We don't deal in medical ethics, if that is what you mean.

Mr. WALGREN. But even medical practice.

Mr. OLIVER. We certainly investigate certain medical practices.

Mr. WALGREN. Did you investigate medical practices with respect to this issue?

Mr. OLIVER. Have we? I am not aware we have investigated this particular practice.

Mr. WALGREN. So it sort of comes down to, looking through the panel here, that Dr. Dickey is the one witness who can testify to what problems arise from a medical practitioner standpoint. You mentioned in your testimony, Dr. Dickey, that the AMA took this position that they should avoid the regular dispensing. Why is that?

Ms. DICKEY. Our concern is, with many of the conflicts of interest that are inherent in practicing medicine today, that physicians should avoid even the appearance of impropriety, and the physician who regularly dispenses drugs has to work perhaps very hard at being sure he avoids that conflict of interest. So, as with many other areas of conflict, when we discuss the medical ethics involved, we recommend that if there is a local ethical pharmacy

where patients' needs can be met, then we avoid the appearance of the conflict of interest by having the patient fill their prescriptions there.

On the other hand, there are a number of places or individual situations where patient care is perhaps best met by a physician who chooses to dispense the drugs himself.

Mr. WALGREN. What kinds of situations would that be?

Ms. DICKEY. Well, if I looked at my own practice, the situations that I could foresee are a large group of geriatric patients who have difficulty with transportation to my office, let alone having then to go on to a pharmacy perhaps some miles distant. Many times mothers who have sick children and, again, have to get to my office and perhaps have other children in tow, if they then have to go and fill a prescription at a pharmacy, it is a marked inconvenience.

Texas has a number of rural areas. I am just outside of Houston, but we have no all-night pharmacies in my town so patients may well go for 12 to 14 hours without having a prescription filled. So there are many instances where patient care might be enhanced by dispensing the medication.

Mr. WALGREN. Let me ask you this. What latitudes do you have under Texas law that you would not have under the Wyden amendment?

Ms. DICKEY. The Texas law allows me to meet the immediate needs of my patients. If I am in a rural area, dispensing of particular drugs, particularly dangerous drugs, narcotic drugs, can be prescribed.

Mr. WALGREN. Does the not-for-profit problem bother you under Texas law at all?

Ms. DICKEY. It doesn't bother me in particular in that I happen to be one of those physicians who chooses not to dispense drugs. I think that physicians certainly will have to at least meet their costs in order to regularly dispense drugs, and probably would acknowledge some profit in that if they were doing it on a regular basis. In Texas, obviously, I can't do that.

Mr. WALGREN. Does the AMA's position that physicians should not engage in it on a regular basis—did the AMA discuss whether it should be for profit or not for profit? I mean not-for-profit is a very real alternative to all practicing physicians, I gather, because it is an add-on to their service that need not necessarily be a profit center for them. Did you in the AMA's consideration deal with the question of whether or not you would support or not support a State law, for example, that would eliminate profit as a possibility in these circumstances?

Ms. DICKEY. No, I cannot say that we discussed that. I think that the situation of the discussion in terms of conflict of interest occurs because of the profit motive here.

Mr. WALGREN. But being against the conflict of interest, you are implicitly against the profit, but you perhaps have not come to grips with whether or not you can recommend eliminating profit completely.

Ms. DICKEY. Not against the profit; against making sure that the patient is not taken advantage of. My concern is that my patients get the best quality of care and that they not be taken advantage

of. If I can meet that by fully disclosing to them that they have several options, one of which, if legal, is to dispense their medication in my office, and if they choose to take advantage of that, then I am still an ethical physician.

Mr. WALGREN. So that is the advantage that you are talking about. Perhaps we can come back to that.

Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Walgren.

Mr. Sikorski. Mr. Madigan.

Mr. MADIGAN. Dr. Dickey, as the representative from the American Medical Association, do you have access to files which would indicate whether or not there are or have been any complaints reaching the American Medical Association, complaints dealing with doctors improperly prescribing drugs?

Ms. DICKEY. Improperly prescribing in terms of what?

Mr. MADIGAN. Prescribing the wrong drug. Prescribing a drug that might, in fact, have a negative health impact upon a patient.

Ms. DICKEY. As staff is reminding me, most complaints go through the State level rather than the American Medical Association, and I am sure that our Office of Legal Counsel and others get complaints just as they do about all manner of other things. To my knowledge, there has not been a significant number of complaints regarding inappropriate prescribing or wrongful prescribing.

Mr. MADIGAN. Is it correct that a particular drug in one dosage might be a proper therapy and in another dosage, an improper therapy?

Ms. DICKEY. Certainly.

Mr. MADIGAN. Are you aware of, or have you ever heard of, instances where pharmacists caught a mistake in a prescription where the recommended dosage obviously was wrong for the patient or the actual medicine being prescribed was wrong for the treatment that was being provided?

Ms. DICKEY. Unfortunately, as Congressman Waxman said, we are all human, and yes, I am aware that there have been errors caught by pharmacists. Likewise, I have caught errors made by pharmacists when they fill my patients' prescriptions. So I don't think that—the number of errors one way or the other is probably going to offset itself. In response, yes, occasional errors are made. I think the number is insignificant.

Mr. MADIGAN. You don't have any idea what that number would be?

Ms. DICKEY. From my own practice, I would venture to say it is a fraction of 1 percent, probably once or twice in a year's time, which is about equivalent to the number of times that I have patients come in and say, "This doesn't look like the same medicine you prescribed last time, Dr. Dickey." Equally, I suppose you could say that there are errors made because they can't read our handwriting, and if we would fill it ourselves, we would avoid that number of errors and help make up for the difference. I think the number is fairly small, sir.

Mr. WAXMAN. If the gentleman would yield to me. Dr. Dickey has the following kind of case come to your attention? A patient may have several different doctors prescribing medications, and when the patient comes in to a pharmacist, the pharmacist who

has the record for that patient discovers that another doctor without having all the information, is prescribing a drug that would have a contraindication with another drug another physician prescribed?

Ms. DICKEY. In fairness to the pharmacist, that is a theoretical check. I don't honestly have any idea how often that happens.

Mr. MADIGAN. When you say a fraction of 1 percent, are you talking about a fraction of 1 percent of all of the prescriptions written by all of the doctors on an annual basis? If that is the case, could you still term that to be an insignificant number?

Ms. DICKEY. The only numbers that I would have available would be to look at my 10 years of practice and to say to you that I get a call of clarification from a pharmacist at most a few times a year, a couple of times a year, and I write hundreds of prescriptions a week. I can't calculate how many that is for you, but I think that number is relatively small, extremely small. Nonetheless, it certainly is a check and it is one that we recognize as an appropriate check when we go through the current system of physicians prescribing and pharmacists dispensing.

Mr. MADIGAN. There are people that are allergic to certain medications and, from time to time in the busy-ness of their practice, doctors do forget that a particular patient is allergic to a particular medication. Is that not correct?

Ms. DICKEY. Absolutely.

Mr. MADIGAN. And the pharmacist, if the patient is a regular customer, has an opportunity to check on that.

Ms. DICKEY. Absolutely, and they perform that check well.

Mr. MADIGAN. And sometimes that is a life-threatening situation. A reaction to penicillin, for example, can be life threatening.

Ms. DICKEY. Yes, it can be.

Mr. MADIGAN. Thank you, Doctor.

Mr. WAXMAN. Thank you, Mr. Madigan.

Let me just pursue a couple points. Dr. Dickey, you are the Chairman of the Council on Ethical and Judicial Affairs for the American Medical Association. If we are now looking down the road and we could project doctors going into the business of selling drugs to their patients, would you think that is a good move for consumers and for doctors? Would you like to see that or are you apprehensive about doctors doing this in a widespread way?

Ms. DICKEY. Are you asking for a personal response from me? My personal feeling is that my job is to diagnose and prescribe, and I prefer to leave the dispensing to the pharmacists. I think that, as demonstrated in some of the opening comments, that is a feeling embraced by many physicians. I feel an obligation as the Chairman of that Council on Ethics to be sure that those physicians who feel that they can best serve their patients by dispensing as well as prescribing understand the conflict of interest and the guidelines that will help them best serve their patients.

Mr. WAXMAN. But unlike Mr. Oliver at the FTC, who seems to feel this is going to be a good move for consumers because it will bring more competition, you don't subscribe to their position that you would like to see doctors actively dispensing medications so they can offer a competitive force to pharmacists?

Ms. DICKEY. I don't perceive it as a real problem. Representative Wyden indicated that indeed, there have been companies out encouraging physicians to dispense for several years.

Mr WAXMAN. Philosophically you differ—even though you have come to the same conclusion—you differ with them.

Ms. DICKEY. Yes.

Mr. WAXMAN. Their position is that competition is good, this is more competition, therefore it is good.

Ms. DICKEY. Well, my basic concern is what is best for the patients, and I think the current system of checks and balances is probably best for the patients, and my personal philosophic feeling would be that most physicians should not be in the dispensing business.

Mr. WAXMAN. Mr. Oliver, we used to have on this subcommittee a man who is now a distinguished Member of the U.S. Senate by the name of Phil Gramm, and we used to have a lot of interesting debates because we would argue that doctors had ethical responsibilities to do things or other people in the health professions had ethical responsibilities. He used to say: "Hogwash! The real key is economics. What we have got to do is produce more competition, and not rely on the medical profession to lower costs, but rely on more competition to lower costs."

Now, you seem to be philosophically close to the idea that competition is good and competition is the best thing for the consumers. What I would like to ask you is: If you have got a physician who can dominate by prescribing the drug and be faced with a conflict of interest which he may not disclose and end the competition because of the position that the physician has vis-a-vis the patient, does that trouble you?

Mr. OLIVER. Mr. Chairman, I don't see how the doctor can dominate, given the number of doctors that are likely to be around, depending upon the location, and given the advertising campaigns that the local pharmacies can run. They can advertise to patients that before they have their prescriptions filled at the doctor's office, they should check the prices out wherever they dispense their drugs, at the drugstore.

Mr. WAXMAN. So you are relying on the consumer being informed that if a doctor is going to dispense a prescription drug, that he is prescribing the drug that is the best for the patient? Now, what if he finds out there is a generic drug? Do you think a patient would know about a generic drug that is equivalent to what the doctor is prescribing, and is a lot cheaper? Would that patient know?

Mr. OLIVER. I would suppose the answer is yes.

Mr. WAXMAN. I suppose if he were on a maintenance schedule of that drug, yes; but otherwise, if it is a short-term prescription, the patient is most likely going to take what the physician prescribes. In fact, the patient will even go to the pharmacist and take what the physician prescribes, isn't that the case?

Mr. OLIVER. First of all, lots of people know there are generic drugs now, as you say, and second, the drugstore industry, the pharmacy industry would educate consumers in the marketplace.

Mr. WAXMAN. So you rely very much on a theory of very sophisticated, informed consumers choosing between different providers

of the same service and then making the choice that is going to be the rational one in his economic self-interest. I would like to ask you this. Isn't there a difference between simply selling a drug and performing a service that a physician ordinarily performs, such as reading an xray, which involves some skill by the physician, or giving an allergy shot, or providing follow-up visits?

These are subject to over-utilization for profit, but they all depend on the skills and judgment of the physician. Once the drug has been prescribed, all that is left is a business transaction of buying the drug and getting that drug as the doctor prescribed it. Isn't that a different kind of thing for the doctor to be doing than some of these other services?

Mr. OLIVER. I don't know that it is, nor do I agree that all the doctors, as seems to be the assumption here, that all the doctors are going to fleece their patients. It seems to me most doctors are probably reliable, decent people and that the bad apples are misusing their position anyway and this is simply an additional way they could misuse it, but they are already making as much improper profit as they can out of some other procedure.

So it seems to me that by eliminating this aspect, we are going to decrease the possible cost benefit to the patient as well as the convenience benefit to the patient.

Mr. WAXMAN. You would dismiss the argument that would be based on the idea that if a patient receives a prescription from his or her physician, that the patient might be too intimidated to refuse to buy that drug from that physician, thereby greatly diminishing competition? You would dismiss that?

Mr. OLIVER. I don't necessarily dismiss it, but it seems to me that if that turns out to be a problem, and it may be a problem in some areas but not other areas, those areas, States can regulate and solve that problem if it turns out to be a problem, but I have no indication that is a national problem that the Federal Government has to deal with.

Mr. WAXMAN. But the FTC is recommending that on a national basis competition is good, and therefore we ought to allow and, in fact, even encourage physicians to dispense these drugs because the FTC thinks it is going to lead to a societal benefit. Now, some of us are looking at this and have some apprehensions, and I think we have some responsibilities to anticipate problems. The question is, as you look down the road, what anticipations do you have?

Mr. OLIVER. We have encouraged consumer choice rather than physician dispensing. What we are saying is at least the Federal Government and the State governments should consider the benefit to consumers before they restrict what has not been shown to be a harmful practice.

Mr. WAXMAN. Are there any more questions? The gentleman from Illinois.

Mr. MADIGAN. Mr. Oliver, where do you live here in the Washington area? What county or——

Mr. OLIVER. In the District.

Mr. MADIGAN. There are all-night drug stores, all-night pharmacies in the District that are also open on holidays and on weekends. Would you think that a medical practitioner who wants to prescribe and sell drugs at a profit in competition, as you are advocat-

ing, should make himself available for that practice on weekends and at night when a person is perhaps likely to run out of a particular medicine that they need very much?

Mr. OLIVER. Do I think they should do that or do I think it should be left to their own discretion as to whether or not they choose to do that?

Mr. MADIGAN. Well, as a matter of convenience—we are all very convenience oriented. If I go to the doctor and the doctor is willing to fill a prescription for me in his office and I have the choice of either getting the prescription right there or driving to a drug store and getting it, as a matter of convenience I am going to get it right there. The doctor obviously has the advantage of the convenience factor from my perspective. But then if I run out of that prescription on a weekend or over a holiday or at 11:00 at night or sometime like that and this is something that I absolutely have to take because of a medical condition, I would have been wiser to have gotten it at the drug store because I suspect that the doctor isn't going to come down on Easter Sunday or Holy Saturday to refill my prescription.

Is that of a concern to you at all? You are advocating a part-time competition, it seems to me.

Mr. OLIVER. I think that doctors and patients will determine those things you are talking about. You assume that I could go and fill my prescription on Easter Sunday. Suppose I bought it from the pharmacy that isn't open on the weekend? Well, maybe the next time I will be more careful and buy it from a pharmacy that is open on the weekend. Likewise, one of the questions I am going to ask my doctor is what happens when I run out, are you available? It seems to me that the patient can deal with that problem as it arises and, again, does not need Federal legislation to solve the problem. Competition will solve that.

Mr. WAXMAN. If I can reclaim my time, which I am sure has expired. If the doctor has asked the patient to come back to get the prescription filled, then that patient may face another bill for a physician visit for that purpose.

Mr. OLIVER. But then the patient, perhaps, would not use that doctor again, will switch doctors. There are an awful lot of doctors out there, Mr. Chairman.

Mr. WAXMAN. If you start off with the assumptions that you start off with, that people are sophisticated, knowledgeable consumers and they find that their doctor is charging them more for drugs and maybe charging some extra for a doctor visit or charging the insurance company for services that need not be performed and a lot of other things, then you are right. Then the economic model would work.

Mr. OLIVER. I have more faith in the American consumer than you have, I guess.

Mr. WAXMAN. Well, I have more faith in human nature trying to take advantage of people who are vulnerable. You don't put people in a position where there is a conflict and then expect them to be saints.

Mr. Wyden, did you want to ask any other questions?

Mr. WYDEN. Yes, thank you. If I might, Mr. Chairman, turn to Dr. Dickey.

Harrison Rogers, the former past president of the AMA said, that doctors were already being bombarded to sell drugs and to work with the repackagers. He made it very clear that this was not an isolated incident but something that was taking place to an alarming degree.

I think the real implication is that this is going to be another step encouraging the over-prescribing of drugs in our society. I want to read you just from an ad and see if you wouldn't agree that this encourages over-prescribing. It is an ad put together by one of the repackagers. The headline says, "Allscrips' In-Office Pharmacy Makes Filling a Prescription as Easy as Writing One." Then at the bottom it says, "Revenue from an average $4 fee, 20 scrips per day, $80; per year, $20,800; 50 scrips per day, $200, per year, $52,000."

Now, I don't know about you, but I have got a pretty busy congressional schedule. If I met with a constituent every 15 minutes for 10 hours a day, I would only meet with 40 constituents. If I was in a physician's situation and I had to evaluate the individual's health plus try to write all the prescriptions that seem to be in this repackager's advertisement, I would have to write a prescription for every patient plus 10 I never even saw.

With this new trend developing with the repackagers and their aggressive sales pitch this is going to be a major stimulant to over-prescribing in our society?

Ms. DICKEY. I don't think that is what we have seen happening. Indeed, the repackagers have been there and have approached many physicians, and the best numbers we have available are that less than 5 percent of physicians have chosen to begin dispensing drugs.

Mr. WYDEN. But the firms say that that is going to increase to 50 percent in the next 5 to 7 years.

Ms. DICKEY. Historically, back in the 1940's as many as 25 to 30 percent of physicians dispensed drugs. The number has gone down to 10 percent in the sixties. I think, indeed, most physicians' responses today have been that we spend the time with our patients to diagnose the ills and appropriately prescribe when it is appropriate to prescribe, and that most physicians have not seen fit to go to dispensing. If they choose to dispense medications, I don't see any indication that they are going to begin to dispense medications that are not needed or necessary.

Mr. WYDEN. Certainly to make $52,000 a year, as the repackagers are saying, you have got to be doing nothing all day every day but writing prescriptions. That is certainly going to encourage over-medication.

My second concern, is about the role of the pharmacist. It seems to me that the pharmacist serves as a system of checks and balances that assures the quality you say you want as a physician. Now, if we permit physician drug sales, aren't we harming the effort to get quality through an independent review?

Ms. DICKEY. I think the AMA has recognized, with their recent joint statement with the National Association of Retail Druggists and Chain Drug Stores, that indeed the current system of checks and balances is a preferred one in most instances.

Mr. WYDEN. But that statement said there should be restrictions on physician sales. It was not a statement endorsing physician sales. Ever since the AMA issued that statement, everything I have ever seen goes 180 degrees from that statement. The statement was a statement limiting physician sales, not one endorsing them.

Ms. DICKEY. That statement recognized the current system of checks and balances and recognized that the feeling was that this should be, if there is a problem, that the appropriate place for the legislation and regulation was at the State level, not at the Federal level; that most States that have chosen to look at this have either found a way to deal with it in their State statutes or, in several instances the States have looked at it and decided there was not a problem and chose not to write any regulations.

Mr. WYDEN. Well, we have been through it with the Federal Trade Commission, and certainly the Federal Trade Commission is working very hard to take these steps to discourage State action.

The last question I would want to ask is for you to explain to me how there is a free choice in a doctor's office when the doctor prescribes on one hand and sells on the other. How does that kind of situation promote competition, free choice and availability in order to find out about the alternatives?

Ms. DICKEY. I think that the free choice comes about, Representative Wyden, in that patients need, number one, to be given the alternative. If a physician chooses to dispense——

Mr. WYDEN. Well, are they doing that now? Are physicians telling them, when they try to make a sale, gee, before you buy from me, you should go out and look around town? Are physicians doing this?

Ms. DICKEY. Physicians are told that those are the guidelines that they should follow.

Mr. WYDEN. But are physicians doing it?

Ms. DICKEY. I have no indication that they are or are not. There are such a small number of physicians that are actually dispensing that I honestly——

Mr. WYDEN. Bob Loomis, one of your members in Oregon who talked about the 200 percent markup, made it very clear that abuses are going on and people are not being told of alternatives. Certainly the consumer wouldn't be buying in that instance if the consumer hadn't been informed right in my home State.

Ms. DICKEY. Unfortunately, I think that the possibility for abuse exists, as it does in many instances of over-utilizing a service or medical care. However, we have not seen indication that there are large numbers of them, and I think that the existing regulations allow for us to go in and get the physician who is gouging or abusing.

Mr. WYDEN. There are virtually no existing regulations anywhere in this country. The FTC is doing everything it can to stop States from taking steps to limit it. This is what is going on in the regulatory system.

Mr. WAXMAN. The gentleman's time has expired.

We have other witnesses to testify, but I do want to inquire if members of the subcommittee wish to ask another round of questions. Several of us have, and I don't want to deny anybody the op-

portunity—although I would certainly like to discourage it. But, I leave it up to the members' judgment.

Mr. Whittaker, you would be next if you want; otherwise, we will move on to the other witnesses.

Mr. WHITTAKER. Mr. Chairman, because I had to be gone and I am not current with the panel, I will forego my time at this time.

Mr. WAXMAN. Does any member wish to inquire? Mr. Bates.

Mr. BATES. Just a couple of quick questions. In trying to determine the basis for legislation—and I think there clearly is the appearance of the conflict of interest—I am more interested in what is actually happening in the doctor's office. Doctors are dispensing drugs, but are they dispensing generic, pre-packaged drugs? Is that what we are dealing with, or are they brand names or what? Do you have any information on that? Does the FTC? Maybe we could get to that later.

Ms. DICKEY. I honestly don't know. I would suggest that probably there are some name brands and some generics.

Mr. BATES. I can't recall. I had heard that it was generics three to one and that the prices the doctors were charging were cheaper than the pharmacies. I think there is this competitive issue between the doctors, though it is on such a small scale I am not sure it is a real threat, but it could grow, I guess. But it seems to be a contention made that doctors were gouging or overcharging. Do we have any evidence of that?

Mr. WYDEN. I can only again repeat that in my home State Bob Loomis, a very experienced physician who is an AMA member, and an AMA delegate, reported recently price markups of 200 percent and was forced to step in and lower the price increases. We have another one in Florida. We have a variety of these anecdotes coming in. Part of the reason we don't have as many as we would like is that there is a problem in getting these cases because of the State boards and confidentiality procedures. But they are certainly coming in at a very rapid pace.

Mr. BATES. I think clothiers and produce mark up 200 percent. Are we going from $1 to $3, or what are we talking about?

Ms. DICKEY. I think we have established at different State levels that physicians can lose their license for overcharging for all manner of things.

Mr. BATES. I don't have a lot of confidence in losing their license, from what I have seen. That is not going to sell me. I would like to know really what is happening and what the charges are and what the profit is because I think what I have seen is that it is higher at the pharmacy, but maybe we can get some evidence later.

Thank you.

Mr. WAXMAN. Mr. Bruce.

Mr. BRUCE. Thank you, Mr. Chairman. Just one question of Dr. Dickey.

I have read your testimony, and I understand from the testimony and a couple of statements that the AMA believes that physicians should not regularly dispense drugs. What I would like to know is how can you at the same time urge physicians not to regularly dispense drugs and testify that you are in opposition to Federal legislation which would prohibit them from doing so?

Ms. DICKEY. Because, Representative Bruce, we believe that, number one, we have not demonstrated a nationwide problem, and number two, if a State is having a problem with physician dispensing, then the appropriate place for regulation should be at the State level rather than at the Federal level. If there is not a nationwide problem, if it is a localized problem, and because the discipline of physicians, the licensing of physicians and pharmacists occurs at the State level, then the appropriate place to address the problem is at the State level.

Mr. BRUCE. Mr. Chairman, just from my own experience in the State of Illinois, we have a very strong physician disciplinary board. Actions are taken every week in our capitol city. I would like also to comment about the ability of the consumer to differentiate. My mother and father are 69 and 67, and I can tell you that if the doctor overcharges them 5 cents, he will know it because he goes to the AARP meetings, he goes to the Senior Citizen's Nutrition Site 5 days a week, and they carry their bottles in and compare with everyone. My father is not a sophisticated consumer, necessarily, but when it comes to drugs and medications that he and my mother are taking, I can tell you that they will drive all over our small community to save $1 a bottle. So they are fairly sophisticated for 69 and 67.

Ms. DICKEY. As will my patients, sir.

Mr. BRUCE. Thank you.

Mr. WAXMAN. Does any member want another round?

If not, we want to thank you very much for your testimony today. We appreciate your contribution to this hearing.

Our second panel includes Dr. Charles West, executive vice president of the National Association of Retail Druggists; Mr. Larry Braden, executive vice president of the Georgia Pharmaceutical Association; and Mr. James Krahulec, vice president for Government and Trade Relations, Rite Aid Corporation.

We want to welcome you to our subcommittee hearing today. Your prepared statements will be made part of the record in full, and we would like to ask you to summarize in no more than 5 minutes.

Dr. West, why don't we start with you?

STATEMENTS OF CHARLES M. WEST, EXECUTIVE VICE PRESIDENT, NATIONAL ASSOCIATION OF RETAIL DRUGGISTS; LARRY L. BRADEN, ON BEHALF OF AMERICAN PHARMACEUTICAL ASSOCIATION; AND JAMES KRAHULEC, ON BEHALF OF NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Mr. WEST. Thank you, Mr. Chairman. I appreciate this opportunity also to testify here today.

I'm Charles West. I currently serve as executive vice president of the National Association of Retail Druggists. We represent the independent retail pharmacists of America.

Let me reiterate at the outset, as Earl Kintner and Phil Jehle did so often in the 1960's and 1970's on behalf of our organization that the issue addressed by H.R. 2093 is not the practice of medicine, but rather the commerce of prescription drugs and restraints in that commerce occasioned by the conduct proscribed by H.R.

2093, which can have fatal consequences for the practice of independent retail pharmacy.

The relationship between the physician and the patient is inherently coercive, and if H.R. 2093 does not pass, then consumers will not have a choice, contrary to what Mr. Oliver has said here today. The consumer does have a choice regarding vitamin purchases, but not in instances where the prescription drugs are involved, because of this inherent coercion.

Physician profiteering for both the prescribing and dispensing of prescription drugs has been well documented in the 1960's and 1970's as inherently unethical, and it leads inevitably to unnecessary prescribing, limited choice of prescription drugs, denial of consumer freedom of choice, higher prices to the consumer, and health consequences related to the elimination of pharmacists from the dispensing of prescription drugs on the one hand and by the dispensing in physician offices by totally unqualified persons.

For example, just this week we received a report from Kansas that a young person who formerly was employed at the soda fountain in the drugstore is now dispensing prescription drugs for a physician just 3 weeks later up the street.

The mid-1980's version of this repudiated practice is the same wolf masquerading in the sheep's clothing of alleged cost containment and a sensible consumer convenience. Tub-thumping on behalf of this practice has increased radically in the past 18 months. I just released a survey of the National Council of State Pharmaceutical Association Executives that found increased physician dispensing and its attendant propaganda in nearly all States.

Make no mistake about the objective of those who are attempting to turn physicians away from their ethical standards. The sole objective, in our view, is to maximize profits through an extension of the prescription monopoly power to a monopoly on dispensing.

In 1964, after conducting 6 days of hearings on this subject, Senator Hart summarized, in part, as follows: "The record is clear that if a doctor decides to allow his financial interest in a drug enterprise to influence his prescribing of medication, then the independent druggist or company in his area cannot compete, no matter how good his service, his products, or his prices. There is nothing he can do to retain or regain this business."

In 1987, it is this same set of concerns that Representative Wyden addressed in his comments entitled "Conflict of Interest" which accompanied the introduction on April 9 of H.R. 2093. Thus the physician exercises total control over the initiation of prescription drug therapy. Such influence, established for public health purposes, can have profound consequences when abused, as in the instance of physicians who dispense prescription drugs for profit.

If all physicians, for example, decided to deny the public the access to a pharmacist, not one tablet or capsule of prescription drugs could be dispensed anywhere in this country in a pharmacy. Such an absolute boycott of pharmacies and pharmacists' services is raised for illustrative purposes, but the specter of such dispensing emerging in 1987 in communities across the country in each of your districts is a difference of degree and not of kind.

If a physician has a quantity of a given drug in the drug room, concern for the economics of inventory control might influence to

use the drug on hand, rather than prescribing a more effective available drug. If there is no economic interest in the pharmacist drug inventory, this consideration disappears, and the physician will most likely prescribe the best possible available product for the patient.

As Dr. Arnold Relman, the editor of the New England Journal of Medicine recently told the American public on an evening network newscast, the bottom line is that "when a physician has a direct financial interest in the prescribing of drugs, this is not in the patient's best interest."

To address these and other concerns now being resurrected by the physician dispensing propaganda, the practices of medicine and pharmacy were established with separate but complementary roles which have endured to the benefit of patients over many centuries of practice. The fourth edition of Kremers and Urdang's "History of Pharmacy" explains the separation of medicine and pharmacy as follows:

"In the 13th Century, the German Emperor Frederick II issued an edict which separated the professions of medicine and pharmacy. This separation acknowledged the fact that the practice of pharmacy required special knowledge, skill, initiative, and responsibility if adequacy of the medicinal needs of the people was to be guaranteed. Forbidding any business relationship between physician and pharmacist, the law established the ethical principle that the only function of the health professions should be professional service and that the sick should not be exploited."

Through appeals to monetary, rather than Hippocratic, interest, it is this deeply rooted bifurcation of medicine and pharmacy that today's prescription drug repackaging companies and their advocates are enticing some physicians to disregard.

For example, Lela Glover of Lake Station, IN in a notarized statement reveals that her physician is charging her $30 for a prescription drug that sells for $19.87 at her local pharmacy, and additionally, she is charged $30 for her office visit each month just to have her prescription refilled.

What can associations do to self-regulate? One recent example is the joint statement of NARD and AMA, which was finalized in February, and importantly the National Association of Chain Drug Stores joined in the issuance of this statement, which has been formally approved by the AMA Board of Trustees. The statement reads: "The National Association of Retail Druggists"——

Mr. WAXMAN. Excuse me, Dr. West.

Mr. WEST. Excuse me.

Mr. WAXMAN. Your time has expired, and we need to hear from everybody. If that is part of your prepared statement, we'll be sure to have that in the record and the transcript of this hearing, and we'll get a chance to share it with our colleagues.

Mr. WEST. Very good.

Mr. WAXMAN. But thank you very much.

Mr. WEST. Thank you, sir.

[Testimony resumes on p. 84.]

[The prepared statement of Mr. West follows:]

Statement of Charles M. West, P.D.
Before the House Energy and Commerce Subcommittee on
Health and the Environment
April 22, 1987

Physician Dispensing for Profit, H.R. 2093

Mr. Chairman, Members of the Subcommittee*:

I am Charles M. West of Alexandria, Virginia. I serve as the Executive Vice President of the National Association of Retail Druggists. With me today is John M. Rector, our General Counsel and Vice President of Government Affairs.

The National Association of Retail Druggists represents owners of nearly 30,000 independent pharmacies, where more than 75,000 pharmacists dispense 70 percent of the nation's prescription drugs. Together, they serve 18 million persons daily and provide 82 percent of Medicaid pharmaceutical services. NARD has long been acknowledged as the sole advocate for the proprietary and professional interests of this vital component of the free enterprise system.

NARD members are primarily family businesses. They have roots in America's communities. The neighborhood independent druggist typifies the reliability, stability, yet adventuresomeness that has made our country great.

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* Henry Waxman (D-CA), Chairman
MAJORITY: (12-D) Representatives Waxman, John Dingell (MI), James Scheuer (NY), Doug Walgren (PA), Mickey Leland (TX), Cardiss Collins (IL), Ron Wyden (OR), Ralph Hall (TX), Wayne Dowdy (MS), Gerry Sikorski (MN), Jim Bates (CA), and Terry Bruce (IL)
MINORITY: (8-R) Representatives Norman F. Lent (NY), Edward Madigan (IL), William Dannemeyer (CA), Thomas Tauke (IA), Dan Coats (IN), Thomas Bliley (VA), and Jack Fields (TX)

We are pleased to appear before the subcommittee. We would like to express our special appreciation to the subcommittee, its chairman and staff for today's hearing which was scheduled so expeditiously after the April 8, 1987 full committee markup which identified the need to more fully explore the need for and the scope of the Wyden amendment, now introduced as H.R. 2093, before it is offered as an amendment to H.R. 1207 or other appropriate legislation scheduled for the consideration of the full House of Representatives.

We do believe that it is important to stress that during the course of the hearings that yielded H.R. 1207, the oversight subcommittee through Congressman Bilirakis solicited materials on the subject of physician dispensing for profit. Various organizations responded in January of 1986, including NARD, which supplied extensive information documenting our concern about this anticompetitive and unethical practice.

Let me reiterate at the outset, as Earl Kintner and Phil Jehle did so often in the 60's and 70's on behalf of NARD, that the issue addressed by H.R. 2093 is not the practice of medicine, but rather the commerce of prescription drugs and restraints in that commerce occasioned by the conduct, proscribed by H.R. 2093, which can have fatal consequences for independent pharmacies and the patients we serve.

Physician profiteering from both the prescribing and dispensing of prescription drugs has been well documented in the 60's and 70's as inherently unethical and leading inevitably to unnecessary prescribing, limited choice of prescription drugs, denial of consumer freedom of choice, higher prices to the

consumer, and health consequences related to the elimination of pharmacists from the dispensing of prescription drugs on the one hand, and by the dispensing in physicians' offices by totally unqualified persons. For example, we received a report this week from Kansas that a young person who formerly was employed at the soda fountain in a drug store was now dispensing prescription drugs for a physician.

The late Senator Phil Hart conducted many of the hearings and introduced legislation with provisions nearly identical to H.R. 2093. One such bill was S. 1575 which was the subject of hearings in 1970, which received widespread support. Typical among the the comments were the following administration officials:

(1) Virginia Knauer, who then as now, was Special Assistant to the President for Consumer Affairs. Speaking for the White House she endorsed S. 1575, on July 29, 1970, and observed in part:

> "There might be some circumstances in which the sale of drugs and devices by medical practitioners may serve the consumer-patient's interest, but the potential for disservice to the consumer far outweighs those occasions when it might benefit him. When the physician stands to gain financially from the drugs and devices he prescribes, a conflict of interest is inherent....Patients of a physician who both prescribes drugs and stands to gain financially from the sale are in effect captive consumers denied the free choice to make their purchase where they choose or to purchase where the price might be lower ...The potential

for the exploitation of patients through higher costs of drugs from the pharmacy in which the prescribing physician has a financial interest is significant. Particularly at this time when medical costs are high and rising, it is imperative for every effort to be made to eliminate possibilities for exploitation of consumers in drug sales and to open all doors to lower drug costs."

(2) The Deputy Attorney General who on August 4, 1970 expressed the Department's endorsement of S. 1575 and observed in part:

"Congressional hearings on two previous bills of similar character (S. 260, 90th Congress; S. 2508, 89th Congress) have developed a record demonstrating that physican ownership of interests in pharmacies and drug companies and certain practices resulting therefore may have an adverse effect on competition and on the public interest and welfare. It is recognized that there may be circumstances in which the sale of drugs or devices by medical practitioners may benefit consumers and, in fact, have the effect of providing such commodities at lower prices. On the other hand, the dangers involved in the sale of drugs or devices by practitioners, or practitioners' ownership of pharmacies or dispensaries, are sufficiently great, and the practical problems of preventing abuses of such relationships sufficiently difficult, to warrant absolute prohibition of the type of financial interest proscribed by the bill."

The mid-1980s version of this reputiated practice is the same old wolf masquerading in the sheep's clothing of alleged cost containment and ostensible consumer convenience. Tub thumping on behalf of this practice has increased radically in the past 18 months. A just-released survey of the National Council of State Pharmaceutical Association Executives found increased physican dispensing and its attendant propaganda in nearly all states.

Make no mistake about the objective of those who are attempting to turn physicians away from their ethical standards. The sole objective, in our view, is to maximize profits through an extension of the prescription monopoly power to a monopoly on dispensing.

In 1964, after conducting six days of hearings on this subject, Senator Hart summarized in part as follows:

> "Appa ..ntly there are doctors--and I emphasize that they are a tiny minority--who use monopoly pr scription power, which was given by law to protect the patient, in order to exploit that patient, to damage independent businessmen and to enrich their own bank balance.
>
> In 1954, the American Medical Association declared MD-ownership of pharmacies unethical, unless the community was remote from any pharmacy. It seems to me that what was declared unethical in 1954 becomes no less unethical today merely because of a change of wording in the AMA code of ethics....The record is clear that if a doctor decides to allow his financial interest in a drug enterprise to influence his prescribing of medication, then the independent druggist or company in his area cannot compete.

(5)

No matter how good his service, his products, or his prices, there is nothing he can do to retain or regain his business."

In 1987, it is this same set of concerns that Representative Wyden addressed in his comments entitled "conflict of interest" which accompanied the introduction on April 9 of H.R. 2093.

There are so many consequences to physicians becoming their own pharmacists. The pharmacist's most important function lies in providing prescription drugs and related services These are drugs which, for public safety, have been restricted by the Food, Drug and Cosmetic Act for use only on the prescription of licensed physicians. It is central to understanding the efficacy of H.R. 2093 to stress that unless the physician generates an order for a drug within its class, the pharmacist is specifically prohibited by law from providing the products and related professional services to the public.

Thus, the physician exercises total control over the initiation of prescription drug therapy. Such influence, established for public health purposes, can have profound consequences when abused, as in the instances of physicians who dispense prescription drugs for profit.

If all physicians, for example, decided to deny the public access to a pharmacist not one tablet or capsule of prescription drugs could be dispensed anywhere in this country.

True, such an absolute boycott of pharmacies and pharmacists' services is raised for illustrative purposes, but the spector of such dispensing emerging in 1987 in communities across the country, in each of your districts, is a difference of degree and not of kind.

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The denial of access to pharmacists by dispensing physicians was especially well addressed by Alan Daniels on behalf of the NCSPAE when he told a Congressional Committee twenty years ago the following:

"When the physician permits the patient to utilize the professional services of the pharmacist, a number of advantages accrue to that patient.

Drawing from the pharmacist's drug inventory, the physician need not concern himself with the economics of his own drug inventory. A prescription drug inventory has no real economic value unless prescribed for and sold to a patient. If a physician has a quantity of a given drug in his drug room, his concern for the economics of inventory control might influence him to use the drug on hand rather than prescribing a more effective available drug. If he has no economic interest in the pharmacist's drug inventory, this consideration disappears and he will most likely prescribe the best possible available product for the patient.

The patient benefits in other ways from the built-in "check and balance" of the physician-pharmacist-patient relationship.

For example, some patients utilize the services of more than one physician and withhold this knowledge from both practitioners. Occasionally, the patient will have prescriptions for medication from both prescribers which, if taken together, might cause harm to the patient. If the prescriber utilizes the pharmacist's services, the pharmacist is in a position to report to the physicians the

possibility of potential danger to the patient and prevent such an event.

Since humans are fallible, the system of doublechecking that exists in the normal physician-pharmacist relationship guards against the ever-present possibility that a prescriber may inadvertently order an unusual dosage schedule. In the event this should happen, it is the pharmacist's responsibility to contact the physician to discuss his actual intent. With today's more potent and specific drug products, the pharmacist adds an additional safeguard to improved, safe, patient care."

As Dr. Arnold Relman, the editor of the New England Journal of Medicine recently told the American public on an evening network newscast, the bottom line is that "When a physician has a direct financial interest in the prescribing of drugs--this is not in the patient's best interests."

To further elaborate on the importance of access to the pharmacist for proper prescription drug therapy, I would bring to the subcommittee's attention the following segment of the article, "The High Cost of Not Complying with Prescription Drugs" by Dorothy Smith, published in the April 1987 edition of Business and Health:

Compliance from the patient's point of view is a series of trade-offs between the daily routine and restrictions imposed by the drug schedule. Patients are most likely to comply with those aspects of the regimen that are least disruptive to their normal routine. It is for this reason that the design of the drug regimen is important and that one-a-day dosing schedules, or schedules that do not require great changes in the normal life style of the patient meet with the greatest success.

Patients forget approximately half of the statements made by physicians almost immediately after the office visit. One reason is that the instructions for the drug therapy usually are given by the physician immediately after the diagnosis, which can cause patient anxiety levels to increase. Consequently, patients are less likely or not able to recall the drug instructions.

Usually it is not until patients are home that they wonder how they were supposed to administer certain medications packaged as inhalers, eye drops or suppositories, and they do not remember if the physician said whether any foods or nonprescription drugs should be taken with the medication. Other questions that surface are those relating to possible side effects, drug storage and alcohol consumption while on the medication.

Patients are more relaxed and receptive to information about the medication once they reach the pharmacy, which constitutes a nonthreatening atmosphere, unlike the physician's office. The primary purpose of the visit to the pharmacy is to obtain the medication, in contrast to the visit to the physician's office, which has the primary purpose of diagnosing the medical complaint.

Too many health professionals believe that patients will take their drugs correctly if a sheet of written medication instructions simply is handed to the patient to take home. But a sheet of paper will not motivate a patient. Studies show that only 30 percent of patients receiving solely a sheet of written instructions gained any cognitive benefit.

To avoid such occurrences, patients should receive personal instructions from both the physician and pharmacist as well as a sheet of written instructions to take home. Patients receiving medication for a chronic condition should receive reinforcement of the prescription instructions in the physician's office and at the pharmacy at least every six months.

As the last person of the health team to have contact with the patient before the patient assumes responsibility for the administration of medication, the pharmacist is in an ideal position to reinforce physician instructions and to answer any questions the patient may have about the drug regimen. The pharmacist also is the only health professional who routinely can show the patient the actual brand of medication and correlate the specific instructions with each drug. This is becoming more important as generic drugs are being used with increasing frequency. If the physician authorizes generic substitution, he or she no longer can tell the patient the color of the tablets or capsules that have been prescribed.

To address these and other concerns, now being resurrected by physician dispensing propoganda, the practices of medicine and pharmacy were established with separate but complementary roles which have endured to the benefit of patients over many centuries of practice. The fourth edition of Kremers and Urdang's History of Pharmacy explains the separation of medicine and pharmacy as follows:

> "Sometime between 1231 and 1240 the German Emperor Frederick II issued an edict that was to be the Magna Charta of the profession of pharmacy. Although promulgated by an emperor of the Holy Roman Empire of the German nation, the edict applied only to that part of his realm called the kingdom of the Two Sicilies....the edict created pharmac as an independent branch of a governmentally supervised health service....
>
> "Separation o_ the pharmaceutical profession from the medical profession. This rule, transgressed now and again by both parties, nevertheless constituted the charter of pharmacy as an independent profession This separation acknowledged the fact that the practice of pharmacy required special knowledge, skill, initiative and responsibility if adequate care of the medicinal needs of the people was to be guaranteed. Forbidding any business relation between physician and pharmacist, the law tried to establish the ethical principles that the only function of the health professions should be professional service, and that the sick should not be exploited."

Through appeals to pecuniary rather than Hippocratic interest it is this deeply rooted bifurcation of medicine and pharmacy that today's prescription drug repackaging companies and their advocates are enticing some physicians to disregard.

Physicians are told that a trip to the pharmacy is a headache that can be by-passed; or that dispensing 'does not require your time or money and you can improve your earnings 10-15%." They are provided a manual and cassette for a drug coordinator; a folk hero of this sordid movement, one Dr. Drennon Stringer of Dallas, Texas, charges that "there is little reason to involve a pharmacist in the course of supplying patients with the vast majority of drugs."

Repeated reference in such propaganda is made to potential patient savings of 60%. This fraudulent representation is based exclusively on an April 1986 study which used an average price of $4.00, based principally on amoxicillin and penicillin prescriptions and compared it to the average cost of $13.61 for the top 100 drugs in a pharmacy. The true economic and health care consequences of such schemes, long ago well documented, are with us again. Through our Doctor Merchant Clearinghouse we have identified the following illustrative recent examples:

(a) Lela Glover of Lake Station, Indiana, in a notarized statement reveals that her physician is charging her $30.00 for a prescription drug that sells for $19.87 at her local pharmacy and additionally, she is charged $30.00 for her refill office visit each month;

(b) a Kentucky physician's pitch for savings to a patient is revealed in the following item from our April 1987 newsletter:

NARD Doctor Merchant Clearinghouse Receives Evidence

The recently formed NARD Doctor Merchant Clearinghouse is already receiving vivid--though not unexpected--examples of the anticompetitive and anti-patient welfare nature of physician dispensing for profit. In one example, an NARD member in Kentucky sent NARD's Doctor Merchant Clearinghouse a promotional letter sent by a dispensing doctor to one of his patients. The direct mail promotion is excerpted below:

Pharmacy Services in Office

Medication Price List

Brand name	*Generic name*	*Dose*	*Quantity*	*Price*
Enduron	Methylclothiazide	5mg	30	$5 80
KTabs		10mEq	60	10.00
Ascripti_	Aspirin, Magnaprin	325mg	30	4.60
			Total	$20.40

Price includes a $1.00 filling fee per prescription

Dear Patient:

We are now offering a discoun' pharmacy service in our office that we are offering to our patients. Your medication profile and prices are listed above.

Prices are wholesale and all discounts are passed on to our patients If a drug is equivalent in a generic form, then generics are used. We are constantly searching for the lowest prices from different distributors.

We think you will find the prices quoted a significant s. vings.

We want you to get the best price available and if you are able to find cheaper prices, please do so. You may wish to purchase only one of the medications at a time.

If you think this service will be of benefit to you, please call Pam the day before you need your prescriptions filled. She will have them ready for yo'i so you will not have to wait.

Please let us know if we can provide any other health care needs.

The pharmacist who shared this promotion with the NARD Doctor Merchant Clearinghouse also included the prices *his* pharmacy charges for the drugs listed in the letter:

Methylclothiazide 5mg	30	$5.19
KTabs	60	8.39
Ascriptin	30	2.59
Total		$16.17

These types of examples are no surprise to NARD, but some observers appear to nave forgotten that the inherent conflict of interest in physician dispensing for profit is bad for competition and bad for patients. Be sure to send any information on physician dispensing for profit to the NARD Doctor Merchant Clearinghouse so that once again NARD can successfully assist political and legislative efforts to expose this disreputable practice.

Somebody is being deceived in the marketing of physician dispensing for profit. Either the repackagers are hoodwinking physicians into believing they are offering low prices, or dispensing physicians *know* the prices are deceiving their patients. Either way it's the patient who suffers. Patients also suffer the breakdown of the traditional pharmacist-dispensing system that protects patient health. Among the problems illustrated in the example above: who is "Pam"--the receptionist, perhaps?

(c) Gaylon Stacy, a Republican state representative from Oklahoma, documents the health consequences of being dispensed the wrong drug by a dispensing physician;

(d) and a recent report of a high school student in a physicians office who dispensed a blood thinner instead of an analgesic.

A recent complaint filed in the U.S. District Court for the southern district of Ohio by Practice Perfect, Inc., of Cincinnati, Ohio, is particularly revealing. It strips the practice of physician dispensing which would be appropriately limited by H.R. 2093 of all its pretense. After derogating the traditional checks and balances provided the public by access to pharmacists as nothing more than an unnecessary trip, item 14 on the complaint states:

"Prescription drug repackaging/wholesaling eliminates (emphasis added) the retail pharmacy marketing level of this distrbution system and enables the consumer/patient to obtain the drug directly from his presiding physician."

This tells it all, like "True Grit", but opposite in character, we are confronted with "True Greed."

Interestingly, this budding industry by most estimates between 2 and 3 years old, seems to have blossomed coincident with the expression of policies at the FTC which defy rational assessment. In recent letters to Georgia and Maryland, its Bureau of Competition gratutiously expressed the belief that profiteering by dispensing physicians is pro-competitive!!!

Incredibly they ignore the pure monopoly power of the physician and liken physician dispensing of prescription drugs to a pharmacist's recommendation of OTC medications which are widely available to the consumer from numerous sources. Further, they naively, or for other unapparent reasons, expressed the view that possible concerns about over-prescribing or limited product selection or other well-documented anti-competitive impacts of such dispensing will be checked by a physician's desire to maintain a reputation as a reliable practitioner. Such views are rivaled only by recent FTC pronouncements that predatory pricing cases are as rare as unicorn sightings.

In early December, we filed an FOIA request with the FTC to attempt to identify any conceivable basis, however wrong-headed, for rejecting all the credible assessments of the past. To date, we have documented that those involved are totally detached from any past FTC or other agency or congressional consideration of the anti-competitive and unethical aspects of physician dispensing for profit. Through persistence and help from appropriate oversight committees, we have identified nothing that would support the FTC views.

We hope that FTC specific concerns regarding physician dispensing will be addressed appropriately in the FTC authorization and appropriation legislation. Already the Senate, on April 7, 1987, clarified that Section 15 of S. 677 requiring advanced notice of proposed FTC intervention includes intervention in the activities of state boards that regulate the practice of pharmacy. Commerce Committee Chairman Hollings took the occasion to observe that "the FTC is espousing a repudiated view on the subject." [physician dispensing for profit]

(14)

Of course, we have been in contact with Chairman Luken and his staff and look forward to working with that subcommittee on this and other aspects of the problem. We will forward, as we have to date, all materials received through our FOIA litigation.

The FTC activities are in part responsible for the firestorm of concern about physician dispensing for profit. It is trouble enough to witness the resurgence of such anti-competitive practices, but to have the FTC, which by law should be protecting small business and the consumer from such unfair competition truly has rung the bell. The expression of such an aberrant view by this federal agency has taken its toll in that it has had a chilling effect upon state legislators and regulators far beyond Georgia and Maryland. Some argue that these two developments are inextricably linked. We have had reports from Oklahoma, Indiana, California, Nevada and Virginia, to mention a few, where bona fide efforts by state officials have been intimidated by the FTC.

In fact, the NARD and NACDS (3-20-87), which represent virtually every retail pharmacy in the United States, have widely distributed a legal memorandum to the states and to the U.S. Congress so that public policy makers can objectively consider the anti-competitive implications of physician dispensing and related public health and safety concerns.

Unfortunately, the evil genie of physician dispensing is out of the bottle and the FTC pulled the cork. Additionally, we have received correspondence from Attorney General Mattox of Texas who shares our concern about FTC meddling in state regulation of physician dispensing for profit.

(15)

One additional point raised by former Senator Dirksen in years past was that perhaps the FTC enforcement would be sufficient to curb such anti-competitive practice. The current FTC Chairman's action on this subject, however, serves only to enhance the need for H.R. 2093.

What of self regulation of this commerce in prescription drugs by professional associations? Until 1954 the AMA principals of medical ethics, Section VII, provided:

> "....an ethical physician does not engage in barter or trade in the appliances, devices or remedies prescribed for patients, but limits the sources of his professional income to professional services rendered to the patient."

In the intervening years, through many congressional and FTC investigations, the AMA diluted its pre-1955 position . One of the highlights of the continuing debate was a brilliant address to the AMA in 1962 by Dr. James H. Sammons, then a councilor of the Texas Medical Association explaining why the Texas Medical Association oppose pharmacy ownership and dispensing by physicians. In part, Dr. Sammons stated:

> "Finally, we feel very strongly that physician ownership of drugstores is adversely affecting medicine in the public eye. It is difficult, if not impossible, to discuss intelligently and convincingly the problems of the socialization and governmentalization of medicine with a patient who knows that the doctor or doctors in town own the drugstores from which he or they are buying their sort. It is bad enough that the doctor's public image has been made to appear, by those forces within our Government which would destroy the private practice of medicine, one of financial

concern primarily and human concern secondarily. It is folly to lend credence to this vicious distortion by adding the factor that we physicians may profit from the sale of the drugs used to obtain the well-being of our patients."

It was with an awareness of this background that we contacted Dr. Sammons, the Executive Vice President of the AMA last summer to renew discussions on this subject.

The text of the NARD/AMA statement was developed in September and October of last year, before the FTC had intervened in Georgia and before the AMA House of Delegates reiterated a comparable concern in December:

"Although there are circumstances in which physicians may ethically engage in the dispensing of drugs, devices, or other products, physicians are urged to avoid regular dispensing and retail sale of drugs, devices, or other products when the needs of patients can be met adequately by local ethical pharmacies or supplies."

The NARD/AMA agreement was finalized in February. Importantly, the National Association of Chain Drug Stores also joined in the issuance of the statement after the AMA Board of Trustees formally approved the agreement which states:

"The National Association of Retail Druggists, the American Medical Association, and the National Association of Chain Drug Stores each believe that the traditional checks and balances provided by a system authorizing physicians to prescribe and pharmacists to dispense prescribed medications best serve the public health and

welfare of the consumer. Individual physicians and pharmacists must make their own decisions on this issue based on applicable laws and the health needs of their patients."*

[* This second sentence is required to dispel any antitrust concerns that could arise if members of any of the three organizations would mistakenly interpret the first sentence to mean that if they disagreed they might jeopardize their membership or suffer other consequences.]

It was this policy statement that Dr. Harrison Rodgers, AMA Immediate Past President, referenced when he was contacted by the New York Times (the text follows):

THE NEW YORK TIMES, SUNDAY, MARCH 22, 1987

Prescription-Drug Sale By Doctors Is Opposed

The American Medical Association said yesterday that it was "inappropriate" for physicians to sell the drugs they prescribe to their patients.

A joint statement by the A.M.A. and the National Retail Druggist Association said that physicians should limit themselves to prescribing drugs and leave the dispensing to pharmacists, an A.M.A. spokesman, Dr. Harrison L. Rogers, said.

According to Dr. Rogers, the associations issued the statement at a time when doctors are being "bombarded" by drug re-packagers to increase their income by selling a limited number of drugs on a regular basis to their patients.

Such a practice, he said, would "make doctors pharmacists and create a conflict of interest."

In certain circumstances, Dr. Rogers said, it was ethical for doctors to sell drugs to their patients, such as when a pharmacist was not nearby.

It was this policy statement which stimulated numerous editorials on the subject including the editorial entitled "Doctors Shouldn't Be Pharmacists" in the March 28, 1987 New York Times, the text of which follows:

NEW YORK TIMES - MARCH 28, 1987

Doctors Shouldn't Be Pharmacists

Should doctors sell drugs to patients as well as prescribe them? The American Medical Association says no, not as a general rule. But more and more physicians are doing so, raising questions of medical ethics and of the need for law. Without question, it's time to legislate.

There are no official figures on how many doctors sell drugs. Pharmaceutical industry officials estimate that 5 percent of the 75,000 physicians in the New York-New Jersey-Connecticut region have begun doing so in the last two years.

The main reason is the drug-repackaging industry, whose members buy drugs in bulk from manufacturers, package them in single-dose containers and sell them to doctors. Repackagers have become more aggressive in recent years, encouraging doctors to stock their products. For doctors, the lure is an increase in income — up to $40,000 a year. For patients, it's convenience — one-stop shopping.

But there are dangers. The physician/pharmacist has an obvious potential conflict of interest. Might he be tempted to write unnecessary prescriptions? Or to prescribe a drug he sells when another he doesn't sell might be preferable? Or to sell brand-name drugs with high markups when cheaper generics are available?

In addition, the A.M.A. fears the loss of the independent pharmacist's ability to act as a "check and balance" on the physician. And many patients would feel pressure, if not outright obligation, to buy drugs from their doctors.

Mindful of those remote situations in which doctors are the only source of prescription drugs, no state has prohibited drug sales by physicians. But since 1980, at least eight have acted to circumscribe the practice. The legal devices range from annual continuing education requirements in pharmacology for physicians to demanding that doctors who sell drugs demonstrate need to do so.

Given the evident dangers and the judgment of the A.M.A. against the practice, every state should begin regulation. Given the availability of independent pharmacists in most places, the tilt should be strongly toward prohibition.

Such ethical policies are important because over time the vast majority of physicians have rejected dispensing of prescription drugs for profit. This new statement will provide timely guidance for them. Like most pharmacists, physicians understand the complementary roles of medicine and pharmacy and appreciate the patient care benefits. But self regulation and ethical guidance fall short of deterring those so motivated by greed that ethical and anti-competitive benchmarks are disregarded. H.R. 2093 does, however, meet the mark and will ensure that these ethical policies are the law of the land.

H.R. 2093 addresses commerce in prescription drugs when dispensed for profit in a manner parallel to the H.R. 1207 provision regulating the commerce of prescription drug samples. In fact, in assessing alleged claims of patient convenience in emergencies, made in the repackagers' propaganda, it is important to recall that one reason that samples were not totally prohibited was to assist physicians in assuring that they could immediately provide a limited supply of a prescription drugs. Likewise, samples were retained to facilitate immediate drug therapy when necessary.

In a July 16, 1986 letter to Chairman Dingell regarding H.R. 4820, AMA Executive Vice President Dr. Sammons presented the eventually adopted case, in part as follows:

> "Drug samples provide many significant benefits for patients. Samples allow a physician to begin therapy immediately, which could be very important particularly on a weekend, holiday, or evening when most pharmacies are not open. Samples also permit a physician to initiate therapy with a small amount of a drug and determine the patient's

therapeutic response and tolerance before prescribing larger amounts for full course of treatment. This is important from the standpoint of drug efficacy, safety and cost."

Of course, H.R. 1207, which was unanimously reported by the Energy and Commerce Committee on April 8, 1987, prohibits the sale of prescription drug samples, as H.R. 2093 would prohibit the sale by physicians of prescription drugs. It is noteworthy that the sale of samples prohibited by H.R. 1207 would cover a physician who provided samples to enhance the sale of prescription drugs or to offset the cost to the patient of purchasing prescription drugs from the physician.

The provisions of H.R. 2093 and those of 1207 dealing with samples address a subject long regulated by the federal government: commerce of prescription drugs. The fact that most states have exercised concurrent jurisdiction is no basis upon which to oppose either set of provisions. As with prescription drug sampling abuses, the abuses of physician dispensing of prescription drugs requires federal legislation. The National Association of Retail Druggists strongly endorses S. 2093 and has several suggestions for the subcommittee's consideration:

(1) A provision clarifying that stricter state laws would not be pre-empted;

(2) A provision specifically authorizing federal district court jurisdiction of violations;

(3) A provision authorizing private relief for those injured by any violations;

(4) A provision establishing penalties identical to those in H.R. 1207 regarding the sale of prescription drug samples by physicians;

(5) A provision that would leave the determination of an "emergency" to the physician, but would eliminate any profit when dispensing for an emergency, as suggested by Rep. Sharp at the 4-8-87 markup of H.R. 1207;

(6) A provision specifying that appropriate state boards that regulate the practice of pharmacy would be responsible for implementing and monitoring the geographic exception for rural, remote areas;

(7) A provision for the divestment of presently held interests inconsistent with H.R. 2093 within one year from the date of enactment. (Approved by Dept. of Justice and recommended by Deputy Attorney General as amendment to Hart bill, 1970.); and,

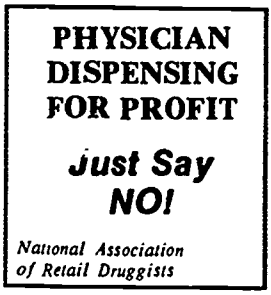
(8) A provision authorizing temporary injunctions where the public interest requires immediate action. (Approved by FTC and suggested by then Chairman Caspar Weinberger, as amendment to Hart bill, 1970.)

In conclusion, Mr. Chairman, NARD supports H.R. 2093 for the following reasons: First, the economic issues are significant today and are likely to become more significant tomorrow, particularly as group medical practice continues to grow; second, the practices proscribed by this bill free the public from restraints of trade which can create artificial price levels and monopoly profits just as effectively as classic price fixing, due to the unique distribution practices which exist in the prescription drug industry; third, the community drugstores across the United States can survive as a viable economic force only if patients everywhere are assured free choice in purchasing prescription drugs; fourth, this bill relates solely to the commerce of prescription drugs and does not affect the

practice of medicine or the states' settled power to regulate this practice; fifth, neither existing federal law, nor FTC enforcement, nor the hope of adequate state law has been demonstrated to provide a realistic solution; and sixth, negotiation and self-regulation has not in the past 33 years shown itself to be the solution to the problems of physician dispensing of prescription drugs for profit.

NARD urges the subcommittee to approve H.R. 2093 and seeks the support of the subcommittee for our recommendations and will assist its members and staff in the refinement of the legislation. Additionally, it is our intention to submit a supplemental statement and exhibits for the Record to the subcommittee addressing other matters relevant to today's subject of physicians dispensing prescription drugs for profit.

On behalf of the Officers, Executive Committee, and members of the National Association of Retail Druggists, we thank you for the opportunity to appear and participate in the formulation of appropriate federal legislation on this matter.



NARD April 22, 1987
Physician Dispensing for Profit
Exhibit List A

Page 1	-	Independent Pharmacy in America
	-	Highlights
Page 2	-	Bilirakis/Wyden questions
	-	Bilirakis 12-17 letter
	-	NARD response 1-23
	-	St. Petersburg incident
	-	5-7-86 NARD letter
	-	NACDS response
Page 3	a)	91st Congress, see section 5, S. 1575
	b)	Re: S. 1575, letters of support
		- Knauer
		- Kleindiest
		- Weinberger
Page 5	a)	NCSPAE survey
Page 11	a)	NAFAC study
	b)	$4 vs. $13
	c)	Lela Glover affidavit
Page 13	a)	Stacy affidavit
	b)	American Druggist article
	c)	PACE report
	d)	Practice Perfect 3-30-87 complaint
Page 14	a)	- NARD FOIA 12-18-86
		- FTC NARD 2-2-87
		- NARD appeal 3-3-87
		- FTC to NARD 3-16-87
		- FTC to NARD 4-14-87
	b)	Senate consideration of sec. 15, S. 677, 4-7-87
Page 15	a)	NARD-NACDS 3-20-87 legal memorandum
	b)	FTC agrees
	c)	Texas letter re: A.G. Mattox
Page 19	a)	Staten Island Advance editorial
	b)	Albany Times Union editorial

NOTE: Additional materials submitted by NARD may be viewed in the subcommittee files for further information.

NARD April 22, 1987
Articles re: Physician Dispensing for Profit
Exhibit List B

1. Fast Bucks and Fat Cats: Drug Repackagers on the Make

2. The Doctors Who Profit from Prescriptions
   Consumer Reports, May 1966

3. Prescribing errors abound, new pharmacist poll finds
   Drug Topics, July 16, 1984, pp. 14-16

4. Warning: Physician Dispensing May Be Bad for Home Health Care
   Home Health Care Pharmacy Bulletin, March-April 1987

5. ACA March 1987 Resolution

6. Louisiana Pharmacists Association "Dear Physician" Letter
   April 10, 1986

7. New Hampshire Pharmaceutical Association Memorandum
   March 16, 1987

8. How Dispensing Doctors Lure an "Iron Curtain"
   by Irving Rubin, Pharmacy Times, April 1987, p. 23

9. Roll Call article, March 16, 1987
   America's most trusted profession

10. "My Experience With the Dispensing Physician"
    by Richard G. Cook, Iola, Kansas

11. Special Newsletter on NARD 1987 Legislative Conference:
    Target: Physician Dispensing for Profit

December 12, 1986

To Whom It May Concern, Or Help:

My physician, Dr. Peter Hamang of 904 West Ridge Road , Hobart, Indiana, Has been selling me my medication which consists of sixty (60) table s of aldactazide 25 mg. His price has been $30.00 for sixty tablets.

In addition to the cost of the medication, Dr. Hamang charges his regular office fee for my visit to him. His fee for an office call is $30.00.

The medicine that I use is the same every month, but I have to go to his office every month before I can purchase any more of my medicine.

The cost of the medication (60 aldactazide tablets 25 mg) at my pharmacy, Dunes Rexall Drugs, is only 19.87 . Therefore , I am forced to pay $10 (Ten dollars) more for my medicine, in addition to an office call fee of $30.00

Lela Clover
4217 Riverpool Road
Lake Station, Indiana

Notary: [illegible]
My Commission expires: 7-12-88
Date: 12/12/86

GAYLON STACY
STATE REPRESENTATIVE
DISTRICT 81
STATE CAPITOL ROOM 540A
OKLAHOMA CITY OKLAHOMA 73105
(405) 521 2711 EXT 225

COMMITTEES
Higher Education
Revenue and Taxation
Insurance
Human Services

House of Representatives

STATE OF OKLAHOMA

April 17, 1987

TO WHOM IT MAY CONCERN:

I, Gaylon Stacy, am a 30-year resident of Edmond, Oklahoma. Presently, I am serving my second term in the Oklahoma Legislature as the elected District 81 member of the Oklahoma House of Representatives. I am also executive vice president of the Oklahoma Lumbermen's Association.

For several days in October, 1986 I had been suffering from a chronic upper respiratory ailment which, based on past experience, was about to result in infected sinuses. On October 21 I was due to chaperone a tour of lumber mills by members of my association. Fearing I might become quite ill on the three-day tour, I went to a family care clinic for which no appointment is required knowing I could obtain quick medical attention. The physician who attended me said he would place me on a regimen of tetracycline, an antibiotic, the name of which I am familiar. No prescription was handed to me by the physician. I assumed I would pick it up, as was customary, at the front desk as I paid the fee. To my surprise a female employee placed before me a vial containing white tablets. I do not know if the employee was a nurse, nurses aide, receptionist, etc. When I inquired to satisfy my surprise, the lady explained it was my prescription and that it had been filled on site. I was not disturbed because it represented a convenience to me due to my tight time schedule.

After a half day of taking the medication as directed (during the tour), I began experiencing some discomfort. Even now it is difficult to accurately describe the feeling. I can only say I became a bit hyperactive and that a slight ringing in my ears became constant. For fully three days I was unable to sleep for more than one or two hours without waking - very unusual for me. I became a bit irritable and my pulse rate seemed to be somewhat higher than normal. I voluntarily ceased taking the medication for a reason I cannot explain for I had no idea it might be the medication which caused me such discomfort. After approximately 18 hours, I began to feel normal with the exception of the fact that I had experienced no relief from the respiratory ailment.

I learned later that the medication prescribed and dispensed at the physician's clinic was not the antibiotic, tetracycline, but a sulpha (spelling?) medication. For many years I have known I am allergic to both sulpha drug and penicillin. I think my chart at the clinic notes those allergies, but I cannot be certain.

Let me erphasize that the physician who attended me did not personally present the container of medication to me. Moreover, I could not testify that he, the physician, personally filled the prescription or personally supervised the filling of the prescription by a member of his staff. That act was not performed in my presence or within my sight.

HOME ADDRESS 2205 WOODFORD WAY EDMOND OKLAHOMA 73034 TELEPHONE (405) 341 1871

Subsequent to my October 21 visit to that clinic and that specific physician, I returned to the clinic to report I had received no relief from the respiratory ailment and asked for additional attention. When the physician entered the examining room and saw it was me, his face fell. He immediately sat down and said something to the effect, "Oh my God, Gaylon, I'm sorry." I emphasize that is not a direct quote, but it definitely is quite similar to his words. He began to apologize profusely. I got the impression he feared I had returned to cause him trouble, which was not at all the case. I simply wanted to get some relief for my ailment.

On this occasion, the physician did, in fact, write a prescription which he handed to me. I do not recall what medication he prescribed this time. But, I did take the prescription to my regular pharmacist where the medication was dispensed.

I share this description of my experience in hopes it might help draw attention to the risk patients may face when the possibility exists that a prescription might be filled and dispensed by untrained and unauthorized persons. I do not know what danger I faced by taking the sulpha medication. I do know, however, that had the medication been penicillin, I would have suffered a traumatic reaction. This I know because I have been told by a physician who attended me earlier in my life that the penicillin reaction I suffered following surgery for appendicitus could easily have resulted in my death had he not administered medication to counteract the reaction.

For what it is worth to the reader, you can be sure I will never take medication which has not been dispensed by a licensed pharmacist unless it is under extreme emergency and under circumstances over which I have no control.

Gaylon Stacy

SUBSCRIBED AND SWORN TO BEFORE ME THIS 17TH DAY OF APRIL 1987.

MY COMMISSION EXPIRES JULY 9, 1990.

ANN M. CONLEY, NOTARY

Mr. WAXMAN. Mr. Braden?

STATEMENT OF LARRY L. BRADEN

Mr. BRADEN. Thank you, Mr. Chairman.

My name is Larry Braden. I am a practicing community pharmacist and also the executive vice president of the George Pharmaceutical Association. I am here today to speak for the American Pharmaceutical Association, the national professional society of pharmacists and to testify in support of H.R. 2093.

I would like to thank you for allowing me to express the thoughts of thousands of pharmacists across the United States who are gravely concerned about the welfare of your constituents and our patients.

APHA strongly opposes medical practitioners dispensing prescription medication to their patients. My comments will focus on three major issues for you to consider.

The first issue is why patient welfare would not be enhanced by the dispensing of prescription medications by medical practitioners. All patients receiving medications are entitled to comprehensive medical and pharmaceutical services. Essential elements of patient care are sacrificed when medications are dispensed by medical practitioners. The separation of prescribing and dispensing responsibilities provides essential checks and balances that result in better therapy and guard against inadvertent prescriber errors, which can be life-threatening to the patient. That monitoring function is lost when the medication is dispensed by the person who prescribes it.

The legal requirements and professional standards for record-keeping, labeling, and dispensing which pharmacists must adhere to are well-founded in good patient care. However, most State Boards of Pharmacy do not have the authority to enter physicians' offices and review the activities of physicians. There is no assurance, therefore, that medical practitioners must meet the same standards of care that pharmacists must when dispensing drugs. This situation weakens protections to which consumers are entitled and circumvents our system of monitoring the actions of patients who may engage in inappropriate usage or abuse of their medications.

APHA is also extremely concerned about the potential conflict of interest that exists when medical practitioners dispense. A typical pharmacy stocks some 3,000 prescription items. The typical dispensing physician stocks less than 50. There is an inherent financial incentive for dispensing physicians to dispense the drug in stock rather than the drug of medical choice. Such a limited but profitable inventory restricts the ability of the physician to provide patients with the most cost-effective and therapeutically effective drug.

Pharmacists concerns about this inherent conflict of interest are being echoed by others, who Mr. Wyden has referred to, in the lay press.

The second issue that we need to address is the vacuous argument that medical practitioner dispensing may enhance competi-

tion and somehow result in greater patient convenience and lower prescription prices.

What could be more competitive than some 50,000 pharmacies in this country actively competing daily for customers and patients for providing their services to those customers and patients? And by comparison, what could be less competitive than a prescriber, in the closed confines of an examination room, advising an elderly or an ill patient that "when you leave, stop by the front desk, and we'll have your medicine ready for you to pick up?"

When the prescriber dispenses, the openly competitive pharmacy market is converted into a closed market in which the patient is controlled by the physician/patient relationship. A subtle, yet powerful, psychological force comes into play, one that compels the typical patient to do what the doctor orders, regardless of the cost.

The claim of potentially lower prescription prices through physician dispensing is dubious and unproven at best. Surveys have consistently shown that the prices are, in fact, higher in the majority of instances. Logic dictates that the cost of repackaging drugs in the quantities of 20 or 30 doses, distributing those drugs to physicians' offices, and the cost of labor provided by physicians, assuming the physician is actually doing the dispensing, when the physician's labor costs are some three times the annual salary of pharmacists, would result in higher prices for consumers.

Competition, which results in better patient services, convenience, and satisfaction, will be maintained in the current physician/pharmacist/patient relationship.

The third thing that we need to address is why we are supporting Federal legislation to deal with this rapidly growing issue. Federal legislation and regulations have been necessary to deal with several areas related to our Nation's drug distribution system, including standards for purity and safety and controls over the prescribing and the dispensing of drugs with a potential for abuse.

The problem facing us today is the recent rapid growth of medical practitioners dispensing drugs because of profit-making motives fueled by some 50 or more companies acting as repackagers of drugs. The issue of medical practitioner dispensing has escalated in the past 3 years into one which threatens to circumvent the many public safeguards incorporated into our pharmacy, drug, and public assistance laws at the State and Federal level.

It has been previously cited in discussions today that one national organization of repackers has stated, as many as 50 percent of all practicing physicians could be dispensing within the next 5 years. The States cannot respond quickly enough to the rapid growth of these commercial ventures, which are determined to capitalize on the absence of adequate controls.

The problems being faced in dealing with this issue can be highlighted by reviewing the recent events in Georgia, which have also been referred to. The majority of States have never addressed the issue of physician dispensing, considering it to be a time-honored practice engaged in by very few physicians, generally in rural settings, who needed to take care of a very few patients under very extenuating circumstances.

The recent development, though, of large-scale commercial operations with slick marketing campaigns designed to sell drugs to

physicians, who in turn will sell them to their patients, led the Georgia General Assembly to enact legislation in 1986 which would establish standards of patient care for dispensing physicians. The Board of Pharmacy was authorized to draft rules and regulations for that, and as you've heard today, the Federal Trade Commission stepped in and has, for all practical purposes, nullified the effect of the Georgia Board of Pharmacy. That has had a very chilling effect on the regulatory process. Today, 1 year later, 1 year following the passage of that legislation, there are no rules or regulations in effect, and no enactment of legislation has occurred.

Mr. Chairman, we appreciate this opportunity to address the issue, and I welcome any questions you might have.

[Testimony resumes on p. 98.]

[The prepared statement of Mr. Braden follows:]

STATEMENT OF AMERICAN PHARMACEUTICAL ASSOCIATION

MR. CHAIRMAN, MY NAME IS LARRY BRADEN. I AM A PRACTICING COMMUNITY PHARMACIST AND ALSO THE EXECUTIVE VICE PRESIDENT OF THE GEORGIA PHARMACEUTICAL ASSOCIATION. I AM HERE TODAY TO SPEAK FOR THE AMERICAN PHARMACEUTICAL ASSOCIATION, THE NATIONAL PROFESSIONAL SOCIETY OF PHARMACISTS AND TO TESTIFY IN SUPPORT OF HR 2093. I WOULD LIKE TO THANK YOU FOR ALLOWING ME TO EXPRESS THE THOUGHTS OF THOUSANDS OF PHARMACISTS ACROSS THE UNITED STATES WHO ARE GRAVELY CONCERNED ABOUT THE WELFARE OF YOUR CONSTITUENTS, OUR PATIENTS.

FOR THE REASONS THAT I WILL DISCUSS HERE TODAY, APHA STRONGLY OPPOSES THE PRACTICE OF MEDICAL PRACTITIONERS DISPENSING PRESCRIPTION MEDICATION TO THEIR PATIENTS. MY COMMENTS WILL FOCUS ON THREE MAJOR ISSUES. FIRST, I WILL DISCUSS WHY THE PATIENT'S WELFARE IS BEST SERVED WHEN ONLY PHARMACISTS DISPENSE. SECOND, I WILL EXPLAIN WHY MEDICAL PRACTITIONER DISPENSING IS ANTICOMPETITIVE. THIRD, I WILL EXPLAIN WHY IT IS NECESSARY TO LIMIT MEDICAL PRACTITIONER DISPENSING AT THE FEDERAL LEVEL, RATHER THAN AT THE STATE LEVEL WHERE SUCH ISSUES ARE TRADITIONALLY ADDRESSED.

AS I NOTED, THE FIRST MAJOR ISSUE TO ADDRESS IS WHY PATIENT WELFARE WILL NOT BE ENHANCED BY THE DISPENSING OF PRESCRIPTION MEDICATIONS BY MEDICAL PRACTITIONERS. APHA HAS LONG SUPPORTED THE SYSTEM OF DISTINCT AND UNIQUE RESPONSIBILITIES WHICH HAS EXISTED BETWEEN THE PROFESSIONS OF MEDICINE AND PHARMACY SINCE THE 13TH CENTURY. PHYSICIANS ARE EXPERTS IN DIAGNOSING HEALTH PROBLEMS AND IN PRESCRIBING THERAPY, WHILE PHARMACISTS, WHO HAVE A MINIMUM FIVE TO SEVEN YEARS OF PHARMACY EDUCATION, ARE EXPERTS IN ENSURING THE RATIONAL USE OF DRUGS AND IN COMMUNICATING THAT INFORMATION TO PATIENTS AND OTHER HEALTH CARE PROFESSIONALS.

WE BELIEVE STRONGLY THAT ALL PATIENTS RECEIVING MEDICATIONS ARE ENTITLED TO COMPREHENSIVE PHARMACEUTICAL SERVICES INCLUDING, BUT NOT LIMITED TO, MAINTAINING PATIENTS' MEDICATION PROFILES, I.E., COMPLETE ,NUAL OR COMPUTER RECORDS OF ANY DRUGS TAKEN BY THE PATIENT, AND COUNSELING PATIENTS. THESE ESSENTIAL ELEMENTS OF PATIENT CARE ARE BEING SACRIFICED WHEN MEDICATIONS ARE DISPENSED BY MEDICAL PRACTITIONERS. THE SEPARATION OF PRESCRIBING AND DISPENSING RESPONSIBILITIES PROVIDES ESSENTIAL CHECKS AND BALANCES THAT RESULT IN BETTER THERAPY AND GUARD AGAINST INADVERTENT PRESCRIBER ERRORS, WHICH CAN BE LIFE-THREATENING TO THE PATIENT. PHARMACISTS ARE RESPONSIBLE FOR MONITORING PRESCRIPTION ORDERS BOTH TO CORRECT INADVERTENT PRESCRIBER ERRORS AND TO PREVENT THE POTENTIALLY DANGEROUS DUPLICATION OF THERAPY AND DRUG INTERACTIONS THAT CAN OCCUR WHEN A PATIENT RECEIVES PRESCRIPTION MEDICATIONS FROM MULTIPLE PRESCRIBERS. THIS MONITORING FUNCTION IS LOST WHEN THE MEDICATION IS DISPENSED BY THE MEDICAL PRACTITIONER RATHER THAN THE PHARMACIST.

A RECENT APPELLATE COURT DECISION RECOGNIZED THE PHARMACISTS' ESSENTIAL AND COMPLEMENTARY ROLE IN THIS SYSTEM OF CHECKS AND BALANCES. THE COURT, IN THE CASE OF RIFF V. MORGAN, NOTED THAT "IF THE CONSENSUS OF THE MEDICAL COMMUNITY IS THAT A SAFETY NET OF OVERLAPPING RESPONSIBILITIES IS NECESSARY TO SERVE THE BEST INTERESTS OF PATIENTS, IT IS NOT FOR THE JUDICIARY TO DISMANTLE THE SAFETY NET AND LEAVE PATIENTS AT THE PERIL OF ONE MAN'S (THE PHYSICIAN'S) HUMAN FRAILTY." (508 A.2D AT 1253, 1254). WE ALSO BELIEVE THAT IT IS OUR RESPONSIBILITY TO ENSURE THAT THIS SAFETY NET IS MAINTAINED FOR THE GOOD OF OUR PATIENTS AND THAT MEDICAL PRACTITIONER DISPENSING BE LIMITED.

APhA FURTHER BELIEVES THAT THE LEGAL REQUIREMENTS AND PROFESSIONAL STANDARDS FOR RECORDKEEPING, LABELING, AND DISPENSING WHICH PHARMACISTS MUST ADHERE TO ARE WELL-FOUNDED IN GOOD PATIENT CARE. HOWEVER, BECAUSE OF THE REGULATORY INSULATION OF PHYSICIANS FROM THE MAJORITY OF STATE BOARDS OF PHARMACY, THERE IS NO ASSURANCE THAT MEDICAL PRACTITIONERS MUST MEET THESE SAME ESSENTIAL STANDARDS. THIS SITUATION WEAKENS THE REGULATORY PROTECTION TO WHICH CONSUMERS ARE ENTITLED. IT ALSO CIRCUMVENTS THE SYSTEM OF MONITORING THE ACTIONS OF PATIENTS WHO MAY ENGAGE IN INAPPROPRIATE USAGE OF THEIR PRESCRIPTION MEDICATIONS. FOR EXAMPLE, THE PHARMACIST'S RECORDKEEPING AND OVERSIGHT FUNCTIONS HELP TO ENSURE THAT PATIENTS ARE NOT INADVERTENTLY ABUSING A DRUG BY OBTAINING RENEWALS AT SHORTER INTERVALS THAN IS WARRANTED OR BY OBTAINING THE SAME OR SIMILAR MEDICATIONS FROM MULTIPLE PRESCRIBERS. THIS SAME OVERSIGHT MAY NOT EXIST WHEN MEDICAL PRACTITIONERS DISPENSE AND RENEWALS ARE DISPENSED BY THEIR OFFICE PERSONNEL.

APhA IS ALSO EXTREMELY CONCERNED ABOUT THE POTENTIAL CONFLICT-OF-INTEREST THAT EXISTS WHEN MEDICAL PRACTITIONERS DISPENSE. THERE IS AN INHERENT FINANCIAL INCENTIVE FOR DISPENSING PHYSICIANS TO NARROW A PATIENT'S THERAPEUTIC OPTIONS TO THOSE MEDICATIONS CARRIED IN THE PHYSICIAN'S LIMITED STOCK, WHICH IN MOST CASES WILL BE FEWER THAN 50 MEDICATIONS. THIS EXTREMELY LIMITED BUT PROFITABLE INVENTORY RESTRICTS THE PHYSICIAN'S ABILITY TO PROVIDE PATIENTS IN EVERY INSTANCE WITH THE MOST COST-EFFECTIVE AND THERAPEUTICALLY EFFECTIVE DRUG. THIS CAPACITY OF THE PHYSICIAN TO SELECT FROM A MYRIAD OF DRUG PRODUCTS WHEN PRESCRIBING

IS AN ASPECT OF OUR HEALTH CARE THAT HAS MADE OURS ONE OF THE BEST HEALTH CARE SYSTEMS IN THE WORLD. WHEN PHYSICIANS WRITE PRESCRIPTION ORDERS TO BE DISPENSED AT PHARMACIES, THE CHOICES OF THERAPY ARE BROADENED TO THE THOUSANDS OF DRUG PRODUCTS, DOSAGE STRENGTHS, AND DOSAGE FORMS THAT PHARMACISTS MAINTAIN FOR THEIR PATIENTS. WITH PRESCRIPTION ORDER IN HAND, PATIENTS THEN HAVE THE ABILITY TO SHOP FOR A PRICE AND SERVICE THAT THEY FEEL IS FAIR. ALSO, CONSIDERING THAT DISPENSING PHYSICIANS LIKELY WILL CARRY ONLY ONE BRAND OF A MULTI-SOURCE PRODUCT, PATIENTS WILL NO LONGER HAVE A CHOICE OF BRAND OR GENERIC MEDICATIONS AS IS CURRENTLY THE CASE IN COMMUNITY PHARMACIES.

PHARMACISTS' CRIES OF CONCERN ABOUT MEDICAL PRACTITIONER DISPENSING ARE BEING ECHOED BY OTHERS OUTSIDE OF PHARMACY AS WELL. THE AMERICAN MEDICAL ASSOCIATION'S (AMA) COUNCIL ON JUDICIAL AND ETHICAL AFFAIRS RECENTLY RECOMMENDED, AND THE AMA HOUSE OF DELEGATES ACCEPTED, THE FOLLOWING STATEMENT: "ALTHOUGH THERE ARE CIRCUMSTANCES IN WHICH PHYSICIANS MAY ETHICALLY ENGAGE IN THE DISPENSING OF DRUGS, DEVICES, OR OTHER PRODUCTS, PHYSICIANS ARE URGED TO AVOID REGULAR DISPENSING AND RETAIL OF DRUGS, DEVICES, OR OTHER PRODUCTS WHEN THE NEEDS OF PATIENTS CAN BE MET ADEQUATELY BY LOCAL ETHICAL PHARMACIES OR SUPPLIERS." IN A FEBRUARY 12 CBS NEWS INTERVIEW, DR. ARNOLD RELMAN, HIGHLY ESTEEMED EDITOR OF THE NEW ENGLAND JOURNAL OF MEDICINE, ECHOED AMA'S CONCERNS. "(A PHYSICIAN) SHOULD NOT BE A BUSINESSMAN WITH AN INVENTORY OF DRUGS ON HIS HANDS THAT HE WANTS TO SELL YOU AT A PROFIT." DR. RELMAN SAID. "THE RISK IS THAT A PARTICULAR DRUG WILL BE USED WHEN IT MAY NOT BE THE BEST DRUG OR WHEN YOU

MAY NOT NEED A DRUG AT ALL." MOREOVER, THE HEALTH CARE FINANCING ADMINISTRATION HAS RECOGNIZED IN ITS REGULATIONS RELATING TO REIMBURSEMENT FOR DRUGS UNDER MEDICAID THE POTENTIAL FOR ABUSE WHEN PRESCRIBERS ALSO DISPENSE. HCFA'S MEDICAL ASSISTANCE MANUAL STATES, "PHYSICIANS ARE PROFESSIONALS WHO GAIN THEIR LIVELIHOOD FROM THE PRACTICE OF MEDICINE. ACCORDINGLY, IT MAY BE HELD THAT THEY SHOULD NOT ALSO PROFIT FROM A PHARMACY PRACTICE, PARTICULARLY WHEN THE DRUGS THEY SELL ARE ALSO PRESCRIBED BY THEM."

THESE CONCERNS REGARDING PRACTITIONER DISPENSING ARE BEING EXPRESSED OUTSIDE OF THE PHARMACY-MEDICAL ARENA AS WELL. A RECENT EDITORIAL IN THE NEW YORK TIMES CONDEMNED THE PRACTICE OF PHYSICIAN DISPENSING BECAUSE OF ITS INHERENT CONFLICT-OF-INTEREST. THE PUBLIC'S CONCERNS HAVE BEEN FURTHER AIRED BY OTHER SEGMENTS OF THE NEWS MEDIA, INCLUDING THE WALL STREET JOURNAL AND NATIONAL TELEVISION.

WE ARE EXTREMELY CONCERNED ABOUT THE UNNECESSARY RISKS TO OUR PATIENTS' WELFARE THAT EXIST AS A RESULT OF MEDICAL PRACTITIONER DISPENSING. ALTHOUGH WE BELIEVE THAT THE MAJORITY OF MEDICAL PRACTITIONERS IN THIS COUNTRY ARE STRONGLY MOTIVATED TOWARD GOOD PATIENT CARE, WE BELIEVE THAT THE REPUTATIONS OF THESE MEDICAL PRACTITIONERS WILL BE TARNISHED BY THE

PRACTICES OF A GROWING NUMBER OF DISPENSING MEDICAL PRACTITIONERS. THE TRADITIONAL SEPARATION OF PHARMACY AND MEDICINE MUST BE MAINTAINED TO PROTECT THE HEALTH AND SAFETY OF OUR PATIENTS.

THE SECOND MAJOR ISSUE I WANT TO ADDRESS IS THE VACUOUS ARGUMENT THAT MEDICAL PRACTITIONER DISPENSING MAY ENHANCE COMPETITION. THE PROPONENTS OF MEDICAL PRACTITIONER DISPENSING ARGUE THAT THE PRACTICE WILL ENHANCE COMPETITION AND SOMEHOW RESULT IN GREATER PATIENT CONVENIENCE AND LOWER PRESCRIPTION PRICES. THERE ARE APPROXIMATELY 50,000 PHARMACIES IN THE UNITED STATES REASONABLY ACCESSIBLE TO VIRTUALLY EVERY CITIZEN. THESE PHARMACIES ACTIVELY COMPETE FOR PATIENTS BY PROVIDING A VARIETY OF PRICE AND SERVICE OPTIONS, INCLUDING CONVENIENT HOURS, DICTATED BY THIS FREE MARKET COMPETITION. THEREFORE, I ASK YOU, WHAT COULD BE MORE COMPETITIVE THAN A NATIONWIDE DISTRIBUTION SYSTEM OF THOUSANDS OF PHARMACIES UTILIZING NEWSPAPERS, TELEVISION AND RADIO, TO ACTIVELY COMPETE FOR PATIENTS? WHAT COULD BE LESS COMPETITIVE THAN A PRESCRIBER IN THE CLOSED CONFINES OF AN EXAMINATION ROOM ADVISING AN ELDERLY OR ILL PATIENT THAT "WHEN YOU LEAVE, STOP BY THE FRONT DESK AND WE'LL HAVE YOUR MEDICINE READY FOR YOU?".

WHEN MEDICAL PRACTITIONERS DISPENSE, THE OPENLY COMPETITIVE PHARMACY MARKET IS CONVERTED INTO A CLOSED MARKET IN WHICH THE PATIENT IS CONTROLLED BY THE PHYSICIAN-PATIENT RELATIONSHIP. THIS SPECIAL PHYSICIAN-PATIENT RELATIONSHIP PRESENTS AN OPPORTUNITY FOR ABUSE WHEN

PHYSICIANS DISPENSE PRESCRIPTION DRUGS FOR PROFIT. PHYSICIANS ARE PERCEIVED AS AUTHORITY FIGURES AND FEW PATIENTS, PARTICULARLY THE ELDERLY, THE LESS EDUCATED AND THE LESS ASSERTIVE, WOULD REJECT A PHYSICIAN'S OFFER TO DISPENSE MEDICATIONS REGARDLESS OF THE PRICE. A SUBTLE, YET POWERFUL PSYCHOLOGICAL FORCE IS AT WORK HERE, ONE THAT COMPELS THE TYPICAL PATIENT "TO DO WHAT THE DOCTOR ORDERS." BY DOING SO, PATIENTS GIVE UP THEIR OPPORTUNITY TO TAKE ADVANTAGE OF COMPETITIVE ELEMENTS IN THE MARKETPLACE, SUCH AS COMPARISONS OF ECONOMIC VALUE, CONVENIENCE, AND PROFESSIONAL SERVICES OF THE MANY PHARMACIES LIKELY AVAILABLE TO THEM. IT IS IMPORTANT TO NOTE HERE THAT UNLIKE MOST OTHER MEDICAL SERVICES, A LARGE PERCENTAGE OF THE COST OF PRESCRIPTION MEDICATION IS PAID FOR BY THE PATIENT OUT-OF-POCKET.

THE CLAIM OF POTENTIALLY LOWER PRESCRIPTION PRICES THROUGH PHYSICIAN DISPENSING IS DUBIOUS AND UNPROVEN AT BEST. BY THE TIME A DISTRIBUTOR ADDS REPACKAGING CHARGES TO EACH BOTTLE OF 20 OR 30 DOSES, LOGIC DICTATES THAT THE COST TO THE PRESCRIBER DRAMATICALLY INCREASES OVER THE COST OF THE IDENTICAL PRODUCT TO THE PHARMACIST. FURTHER, THE NATIONAL AVERAGE SALARY FOR PHYSICIANS IS ABOUT THREE TIMES THAT OF PHARMACISTS. THEREFORE, WE SERIOUSLY QUESTION HOW A CONSUMER CAN BENEFIT ECONOMICALLY BY PAYING FOR DISPENSING SERVICES PROVIDED BY A PHYSICIAN WHOSE LABOR COST IS FAR MORE THAN THAT OF A PHARMACIST.

EVEN THE FEDERAL TRADE COMMISSION HAS, FOR MANY YEARS, REQUIRED THAT OPHTHAMOLOGISTS AND OPTOMETRISTS PRESENT THEIR PATIENTS WITH WRITTEN

PRESCRIPTIONS AND PROVIDE THE PATIENT WITH AN OPPORTUNITY TO SELECT AN EYEGLASS DISPENSER OF HIS OR HER CHOICE. THIS REQUIREMENT IS THE RESULT OF FINDINGS WHICH DEMONSTRATED THE ANTICOMPETITIVE NATURE OF THE PRESCRIBER ALSO PROVIDING THE EYEGLASSES OR CONTACT LENSES. YET, THIS SAME FTC HAS DECIDED THAT COMPETITION IS SOMEHOW ENHANCED WHEN MEDICAL PRACTITIONERS SELL THE MEDICATION THEY HAVE PRESCRIBED. MOREOVER, WITH THE PURCHASE OF EYEGLASSES FROM THE PRESCRIBER, AT LEAST THE PATIENT CAN TELL IF HE OR SHE CAN SEE PROPERLY BEFORE LEAVING THE OFFICE; WITH THE PURCHASE OF MEDICATIONS FROM THE PRESCRIBING MEDICAL PRACTITIONER, THERE IS NO WAY FOR THE PATIENT TO KNOW IF HE OR SHE HAS THE PROPER MEDICATION.

IN SUMMARY, THE CONTEMPORARY PHARMACY MARKETPLACE IS A HIGHLY COMPETITIVE ONE. IF MEDICAL PRACTITIONER DISPENSING BECOMES WIDESPREAD, PHARMACIES LIKELY WILL NO LONGER BE ABLE TO PROVIDE THE HIGH LEVEL OF SERVICES THEY CURRENTLY PROVIDE. WE CONTEND THAT COMPETITION, WHICH RESULTS IN BETTER PATIENT SERVICE, CONVENIENCE, AND SATISFACTION, WILL BE BETTER MAINTAINED IN YEARS TO COME IF THE CURRENT PHYSICIAN/PATIENT/PHARMACIST RELATIONSHIP IS MAINTAINED.

FINALLY, I WOULD LIKE TO ADDRESS WHY WE ARE SUPPORTING FEDERAL LEGISLATION TO DEAL WITH AN ISSUE THAT IS TRADITIONALLY HANDLED AT THE STATE LEVEL. I WILL EXPLAIN BY BRIEFLY SUMMARIZING THE FEDERAL GOVERNMENT'S INVOLVEMENT IN PHARMACY AND THE ACTIVITIES THAT HAVE OCCURRED IN RECENT YEARS BOTH IN GEORGIA AND ELSEWHERE THAT NECESSITATE FEDERAL ACTION AT THIS TIME.

OUR NATION'S DRUG DISTRIBUTION LAWS AND REGULATIONS HAVE EVOLVED OV A PERIOD OF SOME 125 YEARS. FEDERAL LEGISLATION HAS BE.N NECESSARY IN SEVERAL AREAS, SUCH AS ESTABLISHING STANDARDS FOR PURITY AND SAFETY. FEDERAL LEGISLATION ALSO HAS BEEN NECESSARY TO ESTABLISH CONTROLS OVER THE PRESCRIBING AND DISPENSING OF DRUGS WITH A POTENTIAL FOR ABUSE. THE DRUG ENFORCEMENT ADMINISTRATION HAS PROMULGATED NUMEROUS RULES FOR BOTH PHYSICIANS AND PHARMACISTS TO CONTROL THE PRESCRIBING AND DISPENSING OF CONTROLLED SUBSTANCES.

WHILE THE STATES HAVE TRADITIONALLY BEEN VIEWED AS CONTROLLING WHO SHALL PRESCRIBE AND WHO SHALL DISPENSE, BOTH FUNCTIONS ARE ADDRESSED AT THE FEDERAL LEVEL IN SEVERAL AREAS, INCLUDING MEDICARE AND MEDICAID REIMBURSEMENT PROCEDURES AND STANDARDS OF CARE. THE PROBLEM FACING US TODAY, THA" IS THE RECENT RAPID GROWTH OF MEDICAL PRACTITIONERS DISPENSING DRUGS BECAUSE OF PROFIT-MAKING MOTIVES, IS ONE WHICH CANNOT BE QUICKLY AND APPROPRIATELY ADDRESSED BY THE VARIOUS STATES. BECAUSE THE DISTRIBUTION OF DRUGS IS EXPLICITLY ENTWINED WITH THE PROVISION OF SERVICES BY PHARMACISTS, LAWS IN EVERY STATE TIGHTLY AND APPROPRIATELY CONTROL THE DISTRIBUTION OF DRUGS BY PHARMACISTS THROUGH LICENSED PHARMACIES. BECAUSE OF THIS ESTABLISHED AND TIME-PROVEN SYSTEM OF MEDICAL PRACTITIONER AND PHARMACIST HAVING CLEAR AND DISTINCT ROLES, FEW STATES HAVE EVER REVIEWED THE IM"LICATIONS OF LARGE SCALE COMMERCIAL DISPENSING BY THE SAME PERSONS AUTHORIZED TO DIAGNOSE AND PRESCRIBE FOR THE PATIENT. CONSEQUENTLY, STATE BOARDS OF PHARMACY, WHICH ARE THE STATE AGENCIES WITH THE LEGAL AUTHORITY TO CONTROL THE DISPENSING OF MEDICATIONS, HAVE LITTLE OR NO AUTHORITY OVER PHYSICIANS.

FUELED BY SOME 50 OR MORE COMPANIES ACTING AS REPACKAGERS OF DRUGS, THE ISSUE OF MEDICAL PRACTITIONER DISPENSING HAS ESCALATED IN THE PAST THREE YEARS INTO ONE WHICH THREATENS TO CIRCUMVENT THE MANY PUBLIC SAFEGUARDS INCORPORATED INTO OUR PHARMACY, DRUG, AND PUBLIC ASSISTANCE LAWS OVER THE COURSE OF THIS PAST CENTURY AND A QUARTER. ONE NATIONAL ORGANIZATION OF REPACKAGERS HAS STATED THAT AS MANY AS FIFTY PERCENT OF ALL PRACTICING PHYSICIANS COULD BE DISPENSING WITHIN THE NEXT FIVE YEARS. THE STATES CANNOT RESPOND QUICKLY ENOUGH TO THE RAPID GROWTH OF THESE COMMERCIAL VENTURES WHICH SEEM TO BE DETERMINED TO CAPITALIZE ON THE ABSENCE OF ADEQUATE CONTROLS AT THE STATE LEVEL.

ALLOW ME TO SHARE WITH YOU WHAT HAS OCCURRED IN THE STATE OF GEORGIA AS A GOOD EXAMPLE OF THE PROBLEMS FACED BY STATES ATTEMPTING TO ADDRESS THIS ISSUE.

LAST APRIL, AMENDMENTS TO THE GEORGIA CODE CONCERNING PRACTITIONER DISPENSING OF DRUGS BECAME EFFECTIVE. THESE AMENDMENTS, AMONG OTHER THINGS, REQUIRED PRACTITIONERS (I.E. DENTISTS, PHYSICIANS, PODIATRISTS, OR VETERINARIANS) TO COMPLY WITH THE SAME REQUIREMENTS AS PHARMACISTS FOR DISPENSING DRUGS. THE AMENDMENTS ALSO SPECIFICALLY AUTHORIZED THE GEORGIA BOARD OF PHARMACY TO PROMULGATE RULES AND REGULATIONS GOVERNING THE DISPENSING OF DRUGS BY THESE PRACTITIONERS.

CONSISTENT WITH THIS AUTHORITY, LAST OCTOBER THE GEORGIA STATE BOARD OF PHARMACY ISSUED A NOTICE OF INTENT TO ADOPT ON DECEMBER 2, 1986, A NEW

RULE CHAPTER ENTITLED "PRACTITIONER DISPENSING OF DRUGS." THE PURPOSE OF THIS NEW REGULATION WAS TO SPECIFY THE REQUIREMENTS THAT PRACTITIONERS MUST MEET TO LAWFULLY DISPENSE DRUGS IN GEORGIA.

BY A LETTER DATED NOVEMBER 26, 1986, THE STAFF OF THE FEDERAL TRADE COMMISSION SUBMITTED COMMENTS PURPORTING TO EXTOLL THE BENEFITS OF MEDICAL PRACTITIONER DISPENSING AND STATING THAT, AND I QUOTE, "ADOPTION OF THE PROPOSED REGULATION BY AGREEMENT AMONG THE PRACTICING PHARMACISTS WHO ARE MEMBERS OF THE BOARD MAY PLACE THE BOARD AT RISK UNDER THE FEDERAL ANTITRUST LAWS." SUBSEQUENT TO SUBMITTING THIS LETTER TO GEORGIA, THE FTC STAFF ALSO SENT A COMMENT LETTER TO THE MARYLAND STATE BOARD OF MEDICAL EXAMINERS, WHICH WAS CONSIDERING REGULATIONS GOVERNING THE PRACTICE OF PHYSICIAN DISPENSING. IN THIS LETTER, THE FTC TOLD THE MARYLAND MEDICAL BOARD THAT, AND AGAIN I QUOTE, "WE SUGGEST THAT THE BOARD ADOPT A PRESUMPTION THAT, IN GENERAL, PHYSICIAN DISPENSING IS IN THE PUBLIC INTEREST....THE BOARD WOULD BEST SERVE THE PUBLIC INTEREST BY SEEKING TO FACILITATE AND ENCOURAGE PHYSICIAN DISPENSING IN ANY REGULATION IT MAY ADOPT." MOREOVER, ALTHOUGH THE LETTERS TO WHICH I REFERRED WERE ONLY OPINIONS OF THE STAFF, FTC CHAIRMAN DANIEL OLIVER, IN SEVERAL PUBLIC STATEMENTS, APPARENTLY HAS ADOPTED THE STAFF'S POSITION AS HIS OWN. AS A RESULT OF THIS FTC STAFF LETTER TO GEORGIA, WHICH AS YOU CAN SEE CONTAINED A THREAT OF FEDERAL GOVERNMENT PROSECUTION, THE SUBSEQUENT STATEMENTS BY BOTH CHAIRMAN OLIVER AND THE STAFF, AND THE PERSISTENT ACTIVITIES OF REPACKAGERS, WE IN GEORGIA HAVE SEEN THE PASSAGE OF A FULL YEAR WITHOUT ENACTMENT OF ANY REGULATIONS OR ENFORCEMENT OF THE STATUTE WHICH ESTABLISHES STANDARDS TO PROTECT PATIENT WELFARE.
APHA AND PHARMACISTS THROUGHOUT THE UNITED STATES WOULD HAVE PREFERRED TO SEE THE ISSUE OF MEDICAL PRACTITIONER DISPENSING DEALT WITH AT THE STATE LEVEL. HOWEVER, THE ACTIVITIES OF THE REPACKAGERS, WHICH I HAVE DESCRIBED ABOVE, THE FTC'S ILL-CONCEIVED INTRUSION INTO THIS TRADITIONAL AREA OF STATE AUTHORITY, AND THE NEED FOR SWIFT AND UNIFORM ACTION COMPEL US TO SUPPORT FEDERAL LEGISLATION LIMITING MEDICAL PRACTITIONER DISPENSING OF PRESCRIPTION DRUGS IN ORDER TO PROTECT OUR PATIENTS' WELFARE.

THANK YOU FOR THE OPPORTUNITY TO BE HERE TODAY. WE STAND READY TO PROVIDE ANY ASSISTANCE WE CAN TO HELP YOU ENACT APPROPRIATE LEGISLATION TO DEAL WITH MEDICAL PRACTITIONER DISPENSING.

Mr. WAXMAN. Thank you very much, Mr. Braden.
Mr. Krahulec.

STATEMENT OF JAMES KRAHULEC

Mr. KRAHULEC. Thank you, Mr. Chairman and members of the subcommittee. My name is James Krahulec. I am vice president of Government and Trade Relations for Rite Aid Corporation, which is a chain of 1,700 drugstores operating in 22 States east of the Mississippi.

I am here on behalf of the National Association of Chain Drugstores, and we do appreciate the opportunity to comment on this very important legislation.

In our view, the recent increase in the number of physicians who are selling medications to their patients raises very serious questions regarding public health and safety.

For starters, physician dispensing is virtually unregulated, both at the State and Federal level. Only a few States, such as Texas, Massachusetts, Utah, and West Virginia have adequate laws in effect to govern doctor dispensing.

At the Federal level, only one law exists to require accountability on the part of physicians for controlled substances.

For these reasons, we are very concerned about physicians routinely selling prescription drugs to patients.

Moreover, NACDS believes that physician dispensing is anticompetitive and will result in higher medical costs. While there may be some initial convenience involved when the doctor's office sells a prescription to a patient, we do not believe that there are any real cost savings to that consumer when these transactions take place.

For example, in my home State of Pennsylvania, a recent quarterly report from the Pennsylvania Pharmaceutical Assistants Contract for the Elderly, known as the PPACE program, shows that physician dispensing prices are, on the average, higher than the price of drugs dispensed at retail pharmacies.

According to the PPACE program report, dispensing physician claims average $14.33 per claim, while those from the retail pharmacies average $12.92.

Although we do not as yet have additional data on physician drug prices, NACDS believes that there are other significant hidden costs involved when doctors dispense, such as the office visit fee, which can be incurred every time they need to go back for approval on a refill.

We are further troubled by the fact that when doctors dispense prescriptions, they are often selling from a limited stock of 30 to 50 products; thus the patient may not be afforded the opportunity to receive the most appropriate medication or the drug of choice to treat the illness. If the best therapy is not utilized and the illness persists, more costly follow-up visits to the doctor will be necessary.

As indicated in our written statement, Mr. Chairman, we have identified many other major problems associated with physicians selling prescriptions. They include overprescribing and unnecessary dispensing.

We see a loss of freedom of choice on the part of the patient who looks upon the physician as an authority figure and will not chal-

lenge a doctor's decision to dispense a particular drug. Drug chains are also very concerned that physician dispensing will take the doctor away from direct patient care activities so that the actual dispensing functions will be done by untrained receptionists at the front desk.

In addition, NACDS is troubled by the double standard which currently exists in Federal law and in many State statutes that essentially says that patients must be protected when receiving medications from pharmacists in terms of mandated labeling and recordkeeping, but consumers do not need the same level of protection when doctors sell these same drugs.

For example, consumers in many instances do not even receive a written prescription from their doctor when the medication is sold in the physician's office.

To conclude, we are opposed to physician dispensing of drugs for profit. It's a dangerous and largely unregulated practice that usurps the current system of checks and balances that best serves the patient.

We, therefore, endorse the enactment of legislation that establishes minimum uniform standards of labeling, recordkeeping and accountability relative to physician dispensing similar to the requirements currently applied to pharmacists.

We also support legislation establishing appropriate parameters limiting physician dispensing to emergency situations or when there is not a pharmacy within 15 miles of the doctor's office. These key provisions are in Mr. Wyden's bill, and they reflect many of the provisions of the Texas statute which we believe should serve as a model for adoption by other jurisdictions.

We wholeheartedly support Mr. Wyden's bill, because it is reasonable and establishes fair limits on the practice of doctor dispensing. NACDS urges the subcommittee to favorably report the legislation since the States have been intimidated by the Federal Trade Commission from considering appropriate regulation and legislation.

We commend Mr. Wyden for taking a leadership role in this important health care issue, and thank you for your time.

[Testimony resumes on p. 111.]

[Mr. Krahulec's prepared statement follows:]

STATEMENT OF NATIONAL ASSOCIATION OF CHAIN DRUG STORES

INTRODUCTION

THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES, INC., (NACDS) DEEPLY APPRECIATES THE OPPORTUNITY TO TESTIFY ON THE ISSUE OF PHYSICIANS DISPENSING PRESCRIPTION DRUGS TO THEIR PATIENTS FOR PROFIT AND LEGISLATION THAT WOULD ESTABLISH APPROPRIATE LIMITS ON THIS PRACTICE.

NACDS IS A NON-PROFIT TRADE ORGANIZATION, FOUNDED IN 1933, WHICH REPRESENTS THE MANAGEMENT OF 171 CHAIN DRUG CORPORATIONS THAT ARE OPERATING CLOSE TO 20,000 RETAIL DRUG STORES AND PHARMACIES THROUGHOUT THE UNITED STATES. COLLECTIVELY, OUR MEMBERS WERE RESPONSIBLE FOR $30 BILLION IN RETAIL SALES IN 1986 AND MORE THAN 540 MILLION PRESCRIPTIONS WERE DISPENSED TO PATIENTS BY CORPORATE DRUG CHAINS DURING THIS SAME PERIOD. ALSO, 50,000 PHARMACISTS PRACTICE THEIR PROFESSION FOR OUR MEMBER COMPANIES.

MEMBERS OF THE NATIONAL ASSOCIATION OF CHAIN DRUG STORES RANGE IN SIZE FROM OPERATIONS WITH ONLY FOUR STORES TO COMPANIES WITH MORE THAN 1900 RETAIL OUTLETS. THUS, OUR TESTIMONY REFLECTS THE VIEWS OF BOTH SMALL BUSINESSES AND LARGE CORPORATE ENTITIES. WE COMMEND THE CHAIRMAN FOR EXPEDITIOUSLY SCHEDULING THIS HEARING WHICH ADDRESSES A VERY IMPORTANT HEALTH CARE ISSUE.

PHYSICIAN DISPENSING -- A CONTROVERSIAL PRACTICE

THE RECENT, DRASTIC INCREASE IN THE NUMBER OF PHYSICIANS WHO ARE SELLING PRESCRIPTION DRUGS TO THEIR PATIENTS RAISES SERIOUS QUESTIONS REGARDING

PUBLIC HEALTH AND SAFETY AS WELL AS ACCOUNTABILITY AND DRUG INVENTORY CONTROL. IN MOST STATES, THE STORAGE AND DISPENSING OF PRESCRIPTION DRUGS IN PHYSICIAN OFFICES IS VIRTUALLY UNREGULATED, IN COMPARISON TO THE EXTENSIVE RECORDKEEPING, LABELING AND PATIENT INFORMATION REQUIREMENTS THAT RETAIL PHARMACIES MUST FOLLOW. IN ADDITION, PHYSICIAN DISPENSING LACKS THE CRITICALLY NEEDED CHECKS AND BALANCES PROVIDED BY A SYSTEM WHICH AUTHORIZES THE PHYSICIAN TO PRESCRIBE AND THE PHARMACIST TO DISPENSE. WE BELIEVE THAT THIS SYSTEM BEST SERVES THE CONSUMER FOR THE FOLLOWING REASONS. THE PATIENT HAS THE OPPORTUNITY TO DISCUSS WITH THE PHYSICIAN THE THERAPY THAT HAS BEEN PRESCRIBED, AND FURTHER CONSULTATION CAN TAKE PLACE WITH THE PHARMACIST WHEN THE PATIENT IS HAVING THE PRESCRIPTION FILLED. ADDITIONALLY, THESE CHECKS AND BALANCES GIVE THE PHARMACIST THE OPPORTUNITY TO REVIEW THE APPROPRIATENESS OF THE PRESCRIPTION AND TO DETER PRESCRIBING ERRORS THAT DO OCCUR. UNDER A CLOSED SYSTEM IN WHICH THE DOCTOR MAKES A DIAGNOSIS, PRESCRIBES A MEDICATION AND SELLS THE DRUG TO THE PATIENT, THERE IS NO OPPORTUNITY TO REVIEW THE RATIONALE FOR THE PRESCRIPTION.

WHY ARE MORE DOCTORS DISPENSING DRUGS? THE ANSWER IS SIMPLE. AS DEMOGRAPHICS CHANGE IN THE MEDICAL COMMUNITY, MANY PHYSICIANS ARE FEELING AN ECONOMIC PINCH AND ARE SCRAMBLING FOR NEW SOURCES OF INCOME. THE PINCH CAN BE ATTRIBUTED TO SEVERAL DEVELOPMENTS. FIRST, THE NUMBER OF DOCTORS IS INCREASING AT A RATE GREATER THAN THE NUMBER OF PATIENTS. SECONDLY, SINCE 1974, PATIENT VISITS TO PHYSICIANS HAVE DECREASED BY 21 PERCENT. THE RESULT IS THAT PHYSICIAN'S INCOME HAS LEVELED OFF. IN 1986, IT HAS BEEN ESTIMATED THAT THE AVERAGE PRACTITIONER INCOME GREW ONLY BY 1.4 PERCENT WHICH IS 2.4 PERCENT LESS THAN THE COST OF LIVING. FINALLY, PROFESSIONAL

LIABILITY-INSURANCE COSTS AND COMPETITION IN THE HEALTH CARE ARENA HAVE DRAMATICALLY IMPACTED UPON PHYSICIAN INCOME.

ROLE OF REPACKAGERS

TO ENTICE DOCTORS INTO SELLING MEDICATIONS, REPACKAGING COMPANIES HAVE SPRUNG UP OVERNIGHT OFFERING PHYSICIANS PRESCRIPTION DRUG PRODUCTS IN UNIT-OF-USE. THESE REPACKAGERS HAVE WEIGHED IN HEAVILY WITH PROMOTIONAL MATERIALS TO PHYSICIANS TI''T DISPENSING IS AN EASY WAY TO INCREASE PROFITS WITHOUT ANY CAPITAL INVESTMENT. IN MOST CASES, REPACKAGING FIRMS WHICH RECEIVE DRUGS AT A LOWER COST FROM MANUFACTURERS, DO NOT BILL THE PRACTITIONER UNTIL A MONTH AFTER THE INITIAL DELIVERY OF PRODUCTS TO THE PHYSICIAN'S OFFICE. AT THE END OF TI'E MONTH, A REPRESENTATIVE FROM THE REPACKAGING COMPANY WILL VISIT THE DOCTOR'S OFFICE, TAKE INVENTORY AND THEN BILL THE DOCTOR FOR THE DRUGS THAT HAVE BEEN SOLD TO PATIENTS.

THE PROMOTIONAL MATERIALS FROM REPACKAGERS THAT HAVE FLOODED PHYSICIANS OFFICES BOLDLY CLAIM THAT BY DISPENSING PRESCRIPTION DRUGS, PHYSICIANS CAN ADD $30,000 TO $50,000 AND MORE TO THEIR INCOME WHILE SAVING THE PATIENT THE TIME AND TROUBLE OF HAVING TO GO ELSEWHERE TO HAVE THE PRESCRIPTION FILLED.

WHILE MOST PUBLIC POLICY MAKERS AND HEALTH CARE EXPERTS STRONGLY AGREE THAT THE DISPENSING PRACTICES OF PHYSICIANS MUST BE REGULATED, THE DEGREE OF STATE REGULATION VARIES WIDELY OR IS NON-EXISTENT. SOME INDIVIDUALS FEEL THAT PROVISIONS REQUIRING SECURITY AND STORAGE STANDARDS COUPLED WITH THE DEVELOPMENT OF PROTOCOLS WOULD BE SUFFICIENT. OTHERS GO SO FAR

AS TO SAY THAT THE PHYSICIAN DISPENSING SHOULD BE LIMITED UNLESS CIRCUMSTANCES DICTATE A SITUATION WHERE IT WOULD BE DIFFICULT FOR A PATIENT TO GO TO A PHARMACY OR WHERE AN EMERGENCY EXISTS OR IN SITUATIONS WHERE THE DOCTOR WISHES TO TEST THE EFFECTIVENESS OF THE MEDICATION ON A PATIENT BEFORE PRESCRIBING IT. IRONICALLY, MOST OF THESE CASES CAN BE HANDLED RIGHT NOW WITH THE AVAILABILITY OF PHYSICIAN DRUG SAMPLES SO THERE IS REALLY NO MEASUREABLE NEED FOR PHYSICIANS TO DISPENSE PRESCRIPTIONS FOR PROFIT TO THEIR PATIENTS.

NACDS POSITION ON PHYSICIAN DISPENSING FOR PROFIT

WHAT IS OUR POSITION ON PHYSICIAN DISPENSING? NACDS AND ITS CORPORATE MEMBERS ARE OPPOSED TO DOCTORS ROUTINELY SELLING POWERFUL MEDICATIONS TO PATIENTS. WE BELIEVE THAT SUCH A PRACTICE IS INHERENTLY DANGEROUS TO PUBLIC HEALTH DUE TO AN OBVIOUS CONFLICT OF INTEREST THAT EXISTS. WE BELIEVE THAT PHYSICIAN DISPENSING IS ANTI-COMPETITIVE AND CONSTITUTES A HEALTH CARE MONOPOLY THAT WILL RESULT IN HIGHER MEDICAL COSTS. FURTHERMORE, NACDS OBJECTS TO PHYSICIANS DISPENSING FOR PROFIT BECAUSE IT IS UNREGULATED AND PATIENTS ARE DENIED FREEDOM-OF-CHOICE.

THERE ARE APPROXIMATELY 1.6 BILLION PRESCRIPTIONS WRITTEN EACH YEAR IN THE UNITED STATES AND SOME 20 PERCENT OF THESE PRESCRIPTIONS ARE NOT FILLED. REPACKAGERS WILL ARGUE THAT PATIENTS ARE AT RISK IF THEY DO NOT GET THE PRESCRIPTION FILLED. IN MANY CASES, WE WOULD DISAGREE. AMERICA IS AN OVERLY MEDICATED SOCIETY. DRUG ABUSE AND DRUG MISUSE HAVE REACHED EPIDEMIC PROPORTIONS. THE STATISTICS REGARDING DRUG ABUSE ARE GRIM AND COSTLY. IT IS ESTIMATED THAT 10 MILLION AMERICANS REGULARLY USE PRESCRIPTION DRUGS

ILLICITLY AND MORE AMERICANS DIE FROM ABUSING PRESCRIPTION DRUGS THAN FROM USING ILLEGAL SUBSTANCES. ACCORDING TO THE NATIONAL INSTITUTE ON DRUG ABUSE, CRIME, LOST PRODUCTIVITY AND MEDICAL EXPENSES RESULTING FROM DRUG ABUSE COST THE UNITED STATES $49.6 BILLION ANNUALLY. IN TERMS OF DRUG MISUSE, ACCORDING TO A RECENT STUDY PUBLISHED IN "BUSINESS AND HEALTH", APRIL 1987, AS MUCH AS 50 PERCENT OF THE 1.6 BILLION PRESCRIPTIONS DISPENSED ANNUALLY ARE TAKEN INCORRECTLY. THE END RESULT IS A NEEDLESS WASTE OF $13 TO $15 MILLION TO INSURANCE COMPANIES AND THE NATION'S ECONOMY.

THE WASHINGTON POST REPORTED ON OCTOBER 7, 1986, THAT THERE ARE 125,000 DEATHS EACH YEAR AMONG HEART PATIENTS MAINLY FROM MISUSE OF DRUGS THAT ARE DESIGNED TO CONTROL FAULTY HEART RHYTHMS; OF PATIENTS WITH GLAUCOMA, ONLY 42 PERCENT USE DRUGS CORRECTLY; OF ASTHMA PATIENTS 46 PERCENT; OF DIABETICS 48 PERCENT. ACCORDING TO THE WASHINGTON POST, MORE THAN 10 PERCENT OF ALL HOSPITAL ADMISSIONS ARE DIRECTLY RELATED TO PRESCRIPTION DRUG MISUSE.

A RECENT SURVEY BY THE FOOD AND DRUG ADMINISTRATION (FDA) SHEDS FURTHER LIGHT ON THIS CRISIS. ACCORDING TO THE FDA, PHYSICIANS SEE INAPPROPRIATE PRESCRIBING BY OTHER PHYSICIANS AS MORE COMMON THAN SERIOUS ADVERSE REACTIONS TO DRUGS. THE FDA REPORT FURTHER FOUND THAT 10 PERCENT OF PHYSICIANS WHO PARTICIPATED IN THE SURVEY FELT THAT INAPPROPRIATE PRESCRIBING OCCURS FREQUENTLY. ANOTHER KEY FINDING IN THE SURVEY SHOWED THAT DOCTORS HAVE LONG WORKWEEKS, AVERAGING SOME 46.6 HOURS IN DIRECT PATIENT CARE ACTIVITIES. MORE INTERESTING IS THAT THE SURVEY FOUND THAT ONLY 6 PERCENT OF THE PATIENTS REPORTED RECEIVING WRITTEN INFORMATION WHILE IN THE DOCTOR'S OFFICE. THE NATIONAL COUNCIL ON PATIENT INFORMATION

AND EDUCATION (NCPIE) REPORTS THAT NEARLY 70 PERCENT OF PATIENTS SURVEYED SAID THEIR DOCTORS DID NOT TELL THEM ABOUT PRECAUTIONS AND SIDE EFFECTS OR HOW TO TAKE THE MEDICINE.

ALL OF THESE STATISTICS ARE RATHER ALARMING, AND HEALTH CARE PROVIDERS MUST WORK TOGETHER TO [illegible]CT THEM. HOWEVER, ASSUMING THAT DOCTORS ARE PUTTING IN LONG HOURS IN THE CARE OF THEIR PATIENTS AND DO NOT HAVE THE TIME TO ADVISE PATIENTS ABOUT PROPER DRUG USE -- HOW DO THESE PHYSICIANS FIND THE TIME TO SELL MEDICATIONS? IN ALL LIKELIHOOD, IT WILL BE A SITUATION WHERE THE RECEPTIONIST TAKES ON THE RESPONSIBILITY AND FUNCTION OF DISPENSING THE MEDICATION TO THE PATIENT. MORE DISTURBING, WOULD BE IF THE DOCTOR DECIDES TO REDUCE THE TIME SPENT ON DIRECT PATIENT CARE ACTIVITIES IN ORDER TO SELL PRESCRIPTIONS. FOR THE SAKE OF SO-CALLED CONVENIENCE TO THE CONSUMER AND PROFITS TO THE DOCTOR, THE STANDARDS OF PROPER PATIENT CARE ARE BEING REDUCED DRAMATICALLY.

PHYSICIAN PRICES FOR DRUGS -- NO SAVINGS

ON THE QUESTION OF SAVINGS TO THE PATIENT IN TERMS OF PHYSICIAN DISPENSING, ARGUMENTS PUT FORTH BY REPACKAGERS AND THE FEDERAL TRADE COMMISSION (FTC) ARE WEAK AT BEST. IN A DIRECT COMPARISON ANALYSIS OF PHYSICIANS AND DRUG STORE PRICES, A RECENT QUARTERLY REPORT FROM THE PENNSYLVANIA PHARMACEUTICAL ASSISTANCE CONTRACT FOR THE ELDERLY (PACE) PROGRAM SHOWS THAT PHYSICIAN DISPENSING PRICES ARE ON THE AVERAGE HIGHER THAN DRUGS DISPENSED FROM RETAIL PHARMACIES. ACCORDING TO PACE, DISPENSING PHYSICIAN CLAIMS AVERAGED $14.33 PER CLAIM WHILE PHARMACY CLAIMS AVERAGED $12.92 PER CLAIM. NOTWITHSTANDING PRICE, DISPENSING PHYSICIANS WILL BE DISPENSING FROM A

LIMITED STOCK OF 20 TO 30 DRUGS, SO THE PATIENT IS NOT AFFORDED THE OPPORTUNITY TO RECEIVE THE BEST POSSIBLE MEDICATION OR DRUG OF CHOICE TO TREAT THE ILLNESS. IF THE ILLNESS PERSISTS, MORE FOLLOW-UP VISTS TO THE DOCTOR WILL BE NECESSARY. AND AS WE ALL KNOW, THERE IS A CONSIDERABLE FEE OF $25 TO $35 THAT IS ASSOCIATED WITH EACH OFFICE VISIT...SO WHERE ARE THE SAVINGS ON A REFILL WHEN THE PATIENT OR A THIRD PARTY INSURER HAS TO PAY $25 FOR THE OFFICE VISIT, PLUS THE COSTS OF THE DRUG?

PRESCRIPTION DRUG LABELING -- RECORDKEEPING -- DOUBLE STANDARD

THE ISSUE OF PROPER LABELING, STORAGE AND RECORDKEEPING WHEN DOCTORS DISPENSE IS ALSO VERY MURKY AT THE PRESENT TIME. THE FEDERAL FOOD, DRUG AND COSMETIC ACT (SECTION 503(b)) STATES: "ANY DRUG DISPENSED BY FILLING OR REFILLING A WRITTEN OR ORAL PRESCRIPTION OF A PRACTITIONER LICENSED BY LAW TO ADMINISTER SUCH DRUG...(SHALL BEAR A) LABEL CONTAINING...THE NAME AND ADDRESS OF THE DISPENSER, THE SERIAL NUMBER AND DATE OF THE PRESCRIPTION OR OF ITS FILLING, THE NAME OF THE PRESCRIBER, AND, IF STATED IN THE PRESCRIPTION, THE NAME OF THE PATIENT, AND DIRECTIONS FOR USE AND CAUTIONARY STATEMENTS, IF ANY, CONTAINED IN THE PRESCRIPTION."

THE ACT FURTHER SPECIFIES THAT THE MANUFACTURER'S LABEL MUST INCLUDE INFORMATION ABOUT THE PROPER STORAGE OF THE DRUG, SUCH AS LIGHT SENSITIVITY AND TEMPERATURE. HOWEVER, THE FOOD AND DRUG ADMINISTRATION HAS MAINTAINED A POSITION THAT "ALTHOUGH SECTION 503(b) IS APPLICABLE TO PHYSICIANS, WE HAVE LONG CONSIDERED PHYSICIANS <u>WHO DISPENSE</u> DRUGS TO PATIENTS PURSUANT TO A BONA FIDE DOCTOR/PATIENT RELATIONSHIP TO BE EXEMPT FROM STRICT COMPLIANCE WITH THE LABELING REQUIREMENTS FOR PRESCRIPTION DRUGS. AS

RECENTLY AS OCTOBER 1984, STUART L. NIGHTINGALE, M.D. ASSOCIATE COMMISSIONER OF HEALTH AFFAIRS, REAFFIRMED THE AGENCY'S POSITION BY NOTING "WHILE PHYSICIANS ARE SUBJECT TO SECTION 503(b), WE DO NOT BELIEVE THIS SECTION WAS INTENDED ON THE PART OF THE CONGRESS TO INTERFERE WITH THE THEN-WELL-KNOWN DISPENSING PRACTICES OF PHYSICIANS, OR THAT SUCH ONGOING PRACTICES RAISED SAFETY QUESTIONS REQUIRING REMEDIAL ACTION." ALTHOUGH DR. NIGHTINGALE ADMITS THAT DRUGS SHOULD BE PROVIDED IN CONTAINERS THAT WILL PROTECT THEIR INTEGRITY, FDA HAS TRADITIONALLY LEFT ENFORCEMENT OF BOTH PACKAGING AND LABELING TO THE STATES.

SO WHAT WE HAVE IS A SITUATION WHERE THE FDA BELIEVES THAT PATIENTS MUST BE PROTECTED WHEN RECEIVING PRESCRIPTION DRUGS FROM A PHARMACIST IN TERMS OF LABELING, BUT CONSUMERS DO NOT NEED TO BE PROTECTED WHEN THE DOCTOR SELLS THESE SAME DRUGS. PHYSICIAN RECORDKEEPING AND ACCOUNTABILITY REGARDING PRESCRIPTION DRUGS IS CLEARLY NOT ADDRESSED IN THE FOOD, DRUG AND COSMETIC ACT. IN FACT, THE ISSUE OF PHYSICIAN RECORDKEEPING HAD NOT BEEN COVERED BY FEDERAL STATUTE UNTIL CONGRESS APPROVED THE COMPREHENSIVE CRIME CONTROL ACT OF 1984 (P.L. 98-473). AMONG OTHER THINGS, THIS LAW ENHANCED THE AUTHORITY OF DRUG ENFORCEMENT ADMINISTRATION (DEA) TO REQUIRE PHYSICIANS TO KEEP COMPLETE RECORDS REGARDING THE RECEIPT AND DISTRIBUTION OF CONTROLLED SUBSTANCES INCLUDING SAMPLES. NACDS AND OUR CORPORATE MEMBERS ACTIVELY SUPPORTED ENACTMENT OF THE 1984 LEGISLATION, AND AT THE VERY LEAST, WE BELIEVE THE STATES AND THE CONGRESS SHOULD BE DEVELOPING LAWS ESTABLISHING MINIMUM STANDARDS FOR PHYSICIAN DISPENSING -- NAMELY THE SAME STANDARDS THAT APPLY TO RETAIL PHARMACIES.

WHAT ARE THE KEY PROVISIONS OF FEDERAL LEGISLATION TO GOVERN PHYSICIAN DISPENSING? WE BELIEVE THAT THE WYDEN MEASURE IS EXTREMELY REASONABLE. IT ALLOWS FOR PHYSICIAN DISPENSING FOR EMERGENCY SITUATIONS OR WHEN THERE IS NOT A PHARMACY WITHIN 15 MILES OF THE DOCTOR'S OFFICE. THE WYDEN PROPOSAL ALSO PROVIDES FOR SOME SEVEN EXEMPTIONS. WE SUPPORT THE WYDEN BILL AND OFFER SEVERAL SUGGESTIONS TO FURTHER IMPROVE IT.

FIRST, NACDS BELIEVES THAT WHEN PHYSICIANS PRESCRIBE AND DISPENSE, THE DOCTOR SHOULD BE REQUIRED TO SURRENDER THE WRITTEN PRESCRIPTION TO THE PATIENT. THIS WOULD ALLOW THE PATIENT THE CHOICE TO HAVE THE PRESCRIPTION FILLED BY THE DOCTOR OR AT A COMMUNITY PHARMACY AND TO COMPARISON SHOP FOR THE BEST PRICE. OUR RECOMMENDATION IS MODELED AFTER RULEMAKING OF THE FEDERAL TRADE COMMISSION (FTC) WHICH REQUIRES PRESCRIPTIONS FOR EYEGLASSES TO BE GIVEN TO THE PATIENT.

SECOND, DOCTORS THAT DECIDE TO DISPENSE SHOULD BE REQUIRED TO TAKE A MINIMUM NUMBER OF HOURS OF CONTINUING EDUCATION COURSES IN PHARMACY EACH YEAR. FLORIDA HAS SUCH A REQUIREMENT WHICH IS SERVING WELL TO HELP PHYSICIANS KEEP UP WITH THE LATEST DEVELOPMENTS AND CHANGES IN TECHNOLOGY RELATING TO PHARMACEUTICALS AND THE PRACTICE OF PHARMACY. IF AN EDUCATION IN PHARMACY IS NOT RELEVANT TO THE ISSUE OF DOCTORS SELLING PRESCRIPTIONS, WOULD IT NOT ALSO BE REASONABLE FOR PHARMACISTS TO PRESCRIBE WITHOUT HAVING TO STUDY MEDICINE? UNDER THIS ARRANGEMENT, CONSUMERS WOULD HAVE THE CONVENIENCE OF BOTH PRESCRIBING AND DISPENSING IN A RETAIL SETTING WHICH COULD BE OPEN 24-HOURS, BUT WITHOUT THE $25 PHYSICIAN OFFICE VISIT FEE.

CONCLUSION

TO CONCLUDE, NACDS IS VERY CONCERNED ABOUT THE CONTROVERSIAL PRACTICE OF PHYSICIANS DISPENSING FOR PROFIT. IT IS A DANGEROUS AND UNREGULATED PRACTICE THAT USURPS THE CURRENT SYSTEM OF CHECKS AND BALANCES. WE BELIEVE THAT PHYSICIANS SELLING DRUGS FOR PROFIT IS UNETHICAL AND WILL LEAD TO FURTHER OVERPRESCRIBING AND UNNECESSARY DISPENSING THAT WILL RESULT IN HIGHER HEALTH CARE COSTS. IN OUR OPINION, HAVING NO PUBLIC POLICY TO GOVERN AND LIMIT PHYSICIAN DISPENSING IS BAD PUBLIC POLICY. WE, THEREFORE, ENDORSE THE ENACTMENT OF LEGISLATION THAT ESTABLISHES MINIMUM UNIFORM STANDARDS OF LABELING, RECORDKEEPING AND ACCOUNTABILITY RELATIVE TO PHYSICIAN DISPENSING SIMILAR TO THE REQUIREMENTS THAT CURRENTLY APPLY TO PHARMACY. IN ADDITION, NACDS SUPPORTS LEGISLATION ESTABLISHING APPROPRIATE PARAMETERS LIMITING PHYSICIAN DISPENSING TO EMERGENCY SITUATIONS OR WHEN THERE IS NOT A PHARMACY WITHIN 15 MILES OF THE DOCTOR'S OFFICE. OF ALL THE STATE LAWS THAT ARE IN EFFECT ON PHYSICIAN DISPENSING, NACDS BELIEVES THAT THE TEXAS STATUTE IS THE BEST AND WOULD SERVE AS AN EXCELLENT MODEL FOR ADOPTION BY OTHER JURISDICTIONS.

IT IS INDEED UNFORTUNATE THAT RECENT PRONOUNCEMENTS BY THE FEDERAL TRADE COMMISSION (FTC) STAFF IN LETTERS TO GEORGIA AND MARYLAND IN SUPPORT OF PHYSICIAN DISPENSING HAVE HAD A DAMPENING EFFECT ON OTHER STATES CONSIDERING APPROPRIATE LEGISLATION AND REGULATIONS DURING 1987. HAD NOT THE FTC STAFF INTERVENED SO STRONGLY IN GEORGIA AND MARYLAND, WE BELIEVE THAT THIS IMPORTANT HEALTH CARE ISSUE OF PHYSICIAN DISPENSING COULD BE ADEQUATELY ADDRESSED AT THE STATE LEVEL. RECOGNIZING THE UNIQUE ROLE THAT THE STATES HAVE IN ESTABLISHING LAWS TO PROTECT THE HEALTH AND SAFETY OF THEIR

CITIZENS, NACDS HOLDS THE OPINION THAT THE ISSUE OF PHYSICIAN DISPENSING IS BEST LEFT TO EACH STATE TO DECIDE. ABSENT THE OPPORTUNITY TO DO SO BECAUSE OF MEDDLING BY THE FEDERAL TRADE COMMISSION, WE ARE INCLINED TO FAVOR A FEDERAL BILL SUCH AS THE WYDEN AMENDMENT.

WE DEEPLY APPRECIATE THE OPPORTUNITY TO PROVIDE THIS STATEMENT TO THE SUBCOMMITTEE AND NACDS HOPES OUR VIEWS WILL BE GIVEN CAREFUL CONSIDERATION.

THANK YOU.

NEW YORK TIMES - MARCH 28, 1987

Doctors Shouldn't Be Pharmacists

Should doctors sell drugs to patients as well as prescribe them? The American Medical Association says no, not as a general rule. But more and more physicians are doing so, raising questions of medical ethics and of the need for law. Without question, it's time to legislate.

There are no official figures on how many doctors sell drugs. Pharmaceutical industry officials estimate that 5 percent of the 75,000 physicians in the New York-New Jersey-Connecticut region have begun doing so in the last two years.

The main reason is the drug-repackaging industry, whose members buy drugs in bulk from manufacturers, package them in single-dose containers and sell them to doctors. Repackagers have become more aggressive in recent years, encouraging doctors to stock their products. For doctors, the lure is an increase in income — up to $40,000 a year. For patients, it's convenience — one-stop shopping.

But there are dangers. The physician/pharmacist has an obvious potential conflict of interest. Might he be tempted to write unnecessary prescriptions? Or to prescribe a drug he sells when another he doesn't sell might be preferable? Or to sell brand-name drugs with high markups when cheaper generics are available?

In addition, the A.M.A. fears the loss of the independent pharmacist's ability to act as a "check and balance" on the physician. And many patients would feel pressure, if not outright obligation, to buy drugs from their doctors.

Mindful of those remote situations in which doctors are the only source of prescription drugs, no state has prohibited drug sales by physicians. But since 1980, at least eight have acted to circumscribe the practice. The legal devices range from annual continuing education requirements in pharmacology for physicians to demanding that doctors who sell drugs demonstrate need to do so.

Given the evident dangers and the judgment of the A.M.A. against the practice, every state should begin regulation. Given the availability of independent pharmacists in most places, the tilt should be strongly toward prohibition.

Mr. WAXMAN. Thank you very much for your testimony.

Mr. Wyden, why don't we start the questions with you.

Mr. WYDEN. Dr. West, if I might, you draw a distinction between the practice of medicine and commerce of prescription drugs. Could you elaborate on that for the subcommittee?

Mr. WEST. Yes. This approach, the approach of H.R. 2093, does not address the practice of medicine, but the commerce of drugs and trade, much like the Food, Drug and Cosmetic Act.

Mr. WYDEN. Do you believe, Dr. West, that the FTC will leave this area to the discretion of States to regulate? I am very concerned, particularly after these letters that were sent to the States with such strong expressions of discouragement. The FTC is not going to leave this area to the discretion of the States to regulate. I wonder about your position on this.

Mr. WEST. No, we do not believe that—and we feel that the FTC initiative recently is in itself reason for Federal legislation to address the problem.

Mr. WYDEN. Mr. Braden, you mentioned standards that pharmacists are held to that physicians would not be subject to. In particular, you referred to recordkeeping, labeling and dispensing standards. Could you elaborate on this?

Mr. BRADEN. Well, as I addressed in my comments, Mr. Wyden, the standards that have been developed for pharmacy practice have evolved over some 125 years, and those standards are incorporated into the pharmacy laws of virtually every State in the country.

Medical laws do not address the issues of physician dispensing. Therefore, the standards are not imposed on physicians by medical boards or the various State agencies which are responsible for enforcing standards in the medical community. That's the vacuum that I referred to, and that's the vacuum which the repackagers are attempting to capitalize on.

Mr. WYDEN. Let me ask you a question about competition. It deals with the point my colleague from Illinois, Mr. Bruce, raised about the consumer and consumers' informed choices when they are patients in a physician's office. Let's say they have been examined, and have had a course of treatment prescribed, then the physician tries to sell the drug to the patient.

Do you think consumers, after they have been examined, had a course of treatment prescribed, and then when the physician tries to sell the drug, is the consumer going to turn around to the doctor and say, "No, thank you, I don't want to buy the drug from you, Mr. or Ms. Physician"?

Mr. BRADEN. I cannot conceive of that happening. It would be a very rare situation where you would have a patient who is articulate, extremely self-confident, aggressive, in fact, I think, to break that personal relationship between a patient and a physician that develops when one walks into an examining room and submits oneself to the physician.

Mr. WAXMAN. Will the gentleman yield?

Mr. WYDEN. I would be happy to yield to the Chairman.

Mr. WAXMAN. I would ask this question more rhetorically, because I don't think this is the group I particularly want to address it to. Let's say the physician says to the patient, "As part of your

examination, we need to have blood tests and an xray," and he suggests to the patient to go down the hall where the doctor's receptionist will take the xray and will have someone else there on the premises take the blood test.

Now I guess the question I am asking everyone to think about is if that patient, under the model of the FTC, were an informed consumer, that patient may know that he could go to an independent lab and get that test done less expensively with a more reliable person than the receptionist.

If we thought in terms of that economic model of the FTC, the patient would say, "I'm sorry, Doctor, I know you want me to take the blood test and xray, but I know I can get it done less expensively somewhere else, so I'm going to go get it done somewhere else, and you can get the results and evaluate them." I just think that example underscores even more dramatically why patients aren't going to refuse the doctor when the doctor says, "Pick up the medicine on your way out, this is what we are recommending, this is what we are prescribing."

I thank you for yielding.

Mr. WYDEN. Is my time up?

Mr. WAXMAN. It isn't, but if you yield it back, you'd be blessed for taking less time.

Mr. WYDEN. I'd take one more, if you'd let me.

Mr. WAXMAN. The gentleman has another 30 seconds.

Mr. WYDEN. Well, thank you.

Just very briefly, Mr. Braden, does your experience in Georgia lead you to believe that the FTC is going to leave this area to State regulation? In particular, what was the effect of the letter from the Director of the FTC's Bureau of Competition alluding to possible Federal antitrust violations in Georgia?

Mr. BRADEN. That's a two-part question, and in responding to the first part, no. I have seen nothing in print or in the press or anything that would indicate that the FTC is going to back away from that issue and leave the States alone, number one.

Number two, the effect was—I use the term chilling. It was that everything came to a screeching halt. When the FTC comes knocking, it carries a factor of apprehension with it that's probably about three times as high as when IRS comes knocking.

Mr. WYDEN. I couldn't say it any better. Thank you.

Mr. WAXMAN. Thank you.

Mr. KRAHULEC. If I could just expand on that for one moment, Mr. Wyden. As I said in my opening comments, I am responsible for the State government affairs activities in 22 eastern States. Late last year I can tell you that 8, 10, 12 of those States were in the process, at least with the chain drug groups, of developing language along the lines of the Georgia statute. When that FTC letter hit and it was covered very, very heavily in the trade journals, especially within pharmacy—not only that, some groups, and I don't know who, reproduced certain headlines, you know, not the whole letter, but the most telling portions of it and distributed it to members of various State legislatures. There's very little, if any, activity. It just died immediately, and I think that that intrusion by the FTC has virtually killed the issue as a State issue. It's like a misprint on page 1 and the retraction being on page 32. Nobody is

reading page 32, and everybody remembers the publicity from the original letter.

Mr. WYDEN. Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you very much.

Mr. Whittaker.

Mr. WHITTAKER. Thank you, Mr. Chairman.

Mr. Braden, as a professional pharmacist and executive vice president of the Georgia Pharmaceutical Association, speaking for and representing the American Pharmaceutical Association, are you aware of some within your profession, possibly within your own State, who are actively exploring an expanded scope of practice within your profession to allow for consultation to be provided by some pharmacists and limited dispensing thereupon?

Mr. BRADEN. I am aware of the general discussions. I'm sorry, I did not hear the last part of your question.

Mr. WHITTAKER. I am curious if you are aware, within either your professional association on the National or State level, of initiatives that are being undertaken in various States to expand the scope of practice of professional pharmacists to allow them, in certain locales and under certain conditions—a move that I even think may have some value—but to do limited consultation to the patient directly, and then appropriate dispensing within, again, defined parameters?

Mr. BRADEN. Yes, I am.

Mr. WHITTAKER. Do you feel there is an inherent conflict of interest, then, in your testimony here in opposition to physicians having the prerogative of dispensing, where in the same stand you are representing the profession that is attempting to expand their scope of practice to do essentially the same thing?

Mr. BRADEN. No, sir, I do not see a conflict or contradiction.

Mr. WHITTAKER. Would you please explain why.

Mr. BRADEN. Because we are—I have to assume, Mr. Whittaker, that we are referring to the pharmacists prescribing legislation in Florida, perhaps, that——

Mr. WHITTAKER. I honestly do not know what State, but I am aware that there are moves in various States to expand the scope of your practice, which I personally might feel in some cases has value, particularly in rural areas.

Mr. BRADEN. Pharmacists are highly educated, 5 to 7 years college level education in pharmacology, pharmakinetics, all of the processes related to drug and drug therapy and drug distribution. I think it would be short-sighted for our society to not utilize those pharmacists to the best of their abilities.

However, the wholesale usurption of one profession's activities that it is uniquely trained for by another profession because of an absence of laws and regulations that prevents that profession from doing it, I believe is considerably different than a profession expanding its services in order to provide greater services to the patient population.

Mr. WHITTAKER. So your primary concern is the wholesale practice, on the one hand, but limited practice on the other?

Mr. BRADEN. I think that's an appropriate summary.

Mr. WHITTAKER. You feel like the physician dispensing is going to become as wholesale as what the physician dispensing may become?

Mr. BRADEN. The statement has been made repeatedly here today that it's been projected as many as 50 percent or more physicians may be dispensing soon. That is—and that is the transformation of a physician into a pharmacist, if you will. We do see anything in pharmacists, though, that are attempting to convert pharmacists into physicians, by any means.

Mr. WHITTAKER. But you do see, as you acknowledged in your earlier testimony, some movement afoot to either expand the scope of the practice of the pharmacist and/or provide him with postgraduate education, to the extent that he can provide consultation?

Mr. BRADEN. Certainly.

Mr. WHITTAKER. To some percentage, but conceivably less than the 50 percent you are anticipating physicians to acquire?

Mr. BRADEN. Yes, sir. That's proven to be very effective in many different types of health care studies. A pharmacist plays a critical role in patient evaluation and assisting the physicians.

Mr. WHITTAKER. I appreciate your testimony. I would in all candor have to say that I'm afraid you are on very thin ice.

Mr. WAXMAN. Thank you very much.

Mr. Dowdy.

Mr. DOWDY. Thank you, Mr. Chairman.

For any of the witnesses, it's my understanding that in some States—many, many States—a practice called generic substitution is allowed under those States' laws, which permits a pharmacist to substitute a generic version of a brand-name drug a doctor has prescribed. That means that a pharmacist may substitute a different chemical in the same therapeutic class than the one prescribed by the physician.

I've been listening today for concrete evidence of widespread abuses by physicians, who take advantage of their patient/physician relationship to the patient's detriment for their own financial gain. I have not heard what I consider to be a preponderance of the evidence at all, that we have a widespread problem.

But let's look at it from the other side. In these States where generic substitution is allowed, would there not be the same possibility that the pharmacist may take undue advantage of his customer? In other words, couldn't a pharmacist say, "I'm going to substitute this generic drug, because I can have a higher markup and make a little more money, and this customer won't know?"

Is that not a factor possibly for some pharmacists, where they do generic substitution? They might be looking at the profit they make on this drug, as opposed to what the physician prescribed. Yes or no?

Mr. WEST. I cant' give you a yes or no. Can I comment? Is it OK to comment, Mr. Dowdy?

Mr. DOWDY. Yes, indeed.

Mr. WEST. OK. That entire movement, the generic substitution laws were driven by consumers really back during the era when the anti-substitution laws were overturned in the States, and it was for cost-effectiveness, to provide a cheaper product to the consumer. That was the force driving the whole initiative.

Mr. DOWDY. But does this not render the pharmacist vulnerable to the same problem areas that this legislation seeks to address with the physician?

Mr. WEST. I would say no, sir, because of the competitiveness out there that exists in pharmacy today. It is the only—the only real competition that exists in the entire health care segment is in retail pharmacy, where pharmacists have been competing for years and years. And the people are sophisticated, the consumers are. They would not allow this to occur.

Mr. DOWDY. Well, the next part of my question, I don't think I need to ask, but will mention it. I was going to say that on the surface, Mr. Wyden's legislation has some appeal—make the physicians be physicians and pharmacists be pharmacists—and I was going to ask if you would support an effort to broaden Mr. Wyden's legislation to prohibit generic substitution by pharmacists, based on this idea that they could be tempted to make substitutions for financial reasons.

Mr. WYDEN. Would my colleague yield?

Mr. DOWDY. Yes, I'd be happy to yield.

Mr. WYDEN. I know these are complicated concepts, and I've gone through them a few times. Could you tell us what therapeutic substitution is, because I think that's really the question here, and it would be helpful to me and maybe my colleagues. Could you distinguish between therapeutic substitution and generic substitution?

Mr. WEST. Generic substitution is when the two drugs, the same chemical entity are substituted one for another, the same chemical.

Therapeutic substitution would be the interchange within a therapeutic category, not the same chemical entity.

Mr. DOWDY. Who would make that decision in a typical relationship? Would not the pharmacist make the decision as to whether it would qualify as a generic substitution?

Mr. WEST. No, sir. A generic substitution, yes, the pharmacist would make the decision. Therapeutic substitution, there are no laws, to my knowledge, on the books that allow therapeutic substitution.

Mr. WAXMAN. Would the gentleman yield to me?

Mr. DOWDY. Insofar as generic substitution. I was wrong when I was talking about therapeutic substitution. But generic substitution.

Mr. WEST. The pharmacist makes the decision.

Mr. DOWDY. That's right.

Mr. WAXMAN. Would the gentleman yield to me?

Mr. DOWDY. Yes.

Mr. WAXMAN. The pharmacist would make the substitution of a generic drug, which the FDA has approved as being therapeutically equivalent to the brand-name drug. And every time there would be a substitution made, I don't think you could ever find a case where the substitution would result in a higher price to the consumer. It is inevitably a lower cost to the consumer. And that's why States have adopted that ability for the pharmacist to substitute.

With unanimous consent, the gentleman will be given an additional minute. I don't want to take up your time.

But just to complete my statement on this, the generic drug is not only cheaper for the consumer, but a lot of doctors don't know

about generic drugs, because they have been lobbied and propagandized by the brand-name companies, or they knew about the brand-name drug before there was a generic. So that's why they have substitution laws.

It's not a conflict of interest where the pharmacists are doing it for their gain. It's in the law in order that the consumer can benefit from a lower price.

Mr. DOWDY. All right. Well, let me ask it this way. Going on to therapeutic substitution and confining it to therapeutic substitution, would you support changes in this legislation that would outlaw the idea of therapeutic substitution by a pharmacist?

Have any of your groups taken positions on this?

Mr. BRADEN. I can respond if you like. One thing we have to deal with here first of all is a clear understanding of what we're speaking of with therapeutic substitution.

That is a system that has been in effect for some 20 years or more in the country in various health care settings, and in that systems in most instances, you have a committee of physicians and pharmacists who are appointed by that health care setting, be that a hospital, an HMO, or a panel group, and that panel of physicians and pharmacists will look at different categories of drugs. And they may find, for instance, that there are five similar antibiotics that could be used to treat certain types of infections. And then that committee of pharmacists and physicians, working together, may decide that one or two of those antibiotics will handle those situations, and then within that environment, under agreement worked out among all the parties in the best interests of the patient, the pharmacist then is authorized, within the scope of those discussions, to interchange—if the physician writes for this brand, he is authorized to interchange—I'm sorry—for this product, he's authorized to interchange for that product.

The same thing happens in community pharmacy settings on a regular basis. A community pharmacist will call the physician, who has written a prescription for a given item, and say, "Doctor"——

Mr. DOWDY. Does he always call, in a community setting like you're describing?

Mr. BRADEN. Yes, sir. If not, he's in violation of every State law—or the laws of every State that I'm familiar with.

Pharmacists do not independently exchange one drug entity for another. They do not have that authority, to the best of my knowledge, in any State of the Union.

The pharmacists and the physicians work closely together in these roles, and this is very similar, I think, to the standard role that perhaps Mr. Whittaker was talking about, where you have pharmacists and physicians who come together in some type of health care setting, discuss optimal therapy, and develop protocols, if you will, systems which best serve the patients and the economics of that setting and all those kinds of things, but it's always in concert with the physician.

Mr. WAXMAN. The gentleman's time has expired.

Mr. Bliley.

Mr. BLILEY. No questions.

Mr. WAXMAN. Mr. Lent.

Mr. LENT. Thank you, Mr. Chairman.

Mr. Braden, are you concerned with the whole idea here of Federal intrusion into a field that, at least up until now, has been reserved to the States?

Mr. BRADEN. No, sir. I see a need for Federal action in this area, because of the inability of the States to respond to a rapidly growing situation.

Mr. LENT. Well, here we're talking about the Federal Government getting into the regulation of physicians, similar to pharmacists, which have always been regulated at the State level.

Suppose we were to offer an amendment to the Wyden bill to require that pharmacists, when they dispense drugs, substitute the generic form of the drug for the trade name or brand name of that drug. That would be a Federal intrusion, would it not, into what up until now has been a State area?

Mr. BRADEN. I guess it could be construed to be Federal intrusion, yes.

Mr. LENT. And you would probably come before this committee opposed to that sort of an amendment, would you not?

Mr. BRADEN. It's a speculative question, of course. I would say presently, yes, because that has been adequately addressed by the States over a period of some 25 to 30 years.

Mr. LENT. Right. And is this not the same——

Mr. WYDEN. Would my colleague yield?

Mr. LENT. Not at this time. I only have a couple of minutes.

Is this not the same kind of an argument that the medical profession is using here saying, "Hey, wait a minute. This is something that up until now has been reserved unto the States?"

Mr. BRADEN. Were it not for the recent introduction of large-scale commercial operations, as I said in my comments, that seem to be poised to capitalize on this absence of regulatory authority at the State level, I might agree with you.

But the generic substitution laws have taken some 30 years——

Mr. LENT. Well, let me just interrupt and say to you, because my time is short and I want to get to a couple of others——

Mr. BRADEN. Surely.

Mr. LENT [continuing]. That once we open the can of worms vis-a-vis the physicians and start having Federal regulations, it is not going to be too many weeks before we start looking at the pharmaceutical side of the business as well.

I'd like to just skip now to an area that Chairman Waxman brought up about the physician having his own xray machine or the physicians doing their own laboratory tests.

There's nothing in this bill about that, is there?

Mr. BRADEN. Not to my knowledge.

Mr. LENT. And sometimes when you go to a surgeon, he recommends you have surgery.

Mr. BRADEN. Correct.

Mr. LENT. And he recommends that he's got the person that's going to do the surgery.

Mr. BRADEN. That's correct.

Mr. LENT. In all of those situations, you have something of a conflict of interest, do you not?

Mr. BRADEN. I would perceive those situations as being decisions that are made in the process of diagnosing the patient and provid-

ing professional services by the physician that are within the area of his expertise and training.

Mr. LENT. Well, you indicated that you were very concerned about the conflict of interest situation there might be here, where the doctor was dispensing drugs, pharmaceuticals.

When the doctor has an xray, what's the difference? What's the difference if the doctor dispenses the drug, or the doctor has an xray, or the doctor performs a laboratory service, or the surgeon prescribes surgery?

I mean, why are we singling out in this piece of legislation the situation only where the physician dispenses drugs? "Oh, well, that's a conflict of interest." But these other things, they're OK.

Maybe we ought to amend the Wyden bill to prohibit all these other things, too, and at least be consistent.

Would you have any objection to my offering that sort of an amendment?

Mr. BRADEN. Well, I think we're beginning to compare apples and oranges here. There is an established distribution system of drugs in this country that serves the public quite well. It is a combination in pharmacy of the professional services offered by pharmacists through their education and expertise and the selling of a product, vis-a-vis the drug that is dispensed.

Mr. LENT. Now in some States, pharmacists are allowed to actually do their own prescribing of drugs. You're familiar with that?

Mr. BRADEN. To the best of my knowledge, that is primarily in Florida. There is legislation in Florida which allows a pharmacist to select a very limited number of drugs which have a legend on them.

Mr. LENT. Right. And I thought I heard you say in response to Mr. Whittaker's question, that you supported organized pharmacies' efforts to broaden their rights to actually prescribe the drugs.

Mr. BRADEN. No, sir. I said I support organized pharmacies' attempts to expand the services that pharmacists offer to patients.

Mr. LENT. That's OK?

Mr. BRADEN. Yes, sir, and appropriate.

Mr. LENT. But to turn the coin around and allow the physician to dispense the drugs as a convenience to the patient, that you're opposed to?

Mr. BRADEN. I would not advocate pharmacists attempting to become physicians.

Mr. LENT. But the other way around is OK.

Mr. BRADEN. I think, as I understand the situation, the other way around is that physicians are attempting to become pharmacists. And no, we are opposed to that.

Mr. LENT. Oh, OK, OK.

Mr. WAXMAN. The gentleman's time——

Mr. LENT. I think there might be just a germ of hypocrisy there where it would be OK, for pharmacists to seek to intrude into the physician's sphere of influence on a State-by-State level, Florida being one of the other States and other States being in the works, but there is an objection, through this bill, to the physician dispensing the pharmaceuticals; is that correct.

Mr. BRADEN. I think I need to reemphasize, if I may, Mr. Chairman, that in all these instances that have been referred to, the

pharmacists and physicians work together either within the structure of law or within the structure of an organized health care setting to establish such things as the very limited list of drugs which pharmacists may use in Florida for very special circumstances.

Mr. LENT. OK. And that would be the structure of State law?

Mr. BRADEN. That happens to be a State law, yes.

Mr. WAXMAN. The gentleman's time has expired.

Mr. Bruce.

Mr. BRUCE. Thank you, Mr. Chairman.

Mr. West, I noticed in your testimony you used words like "inherently coercive, physician profiteering, inherently unethical, leads inevitably to overprescribing, limited choice of drugs, denial of freedom, higher prices, elimination of pharmacists, and totally unqualified persons dispensing medication."

In light of that testimony, can you tell me why none of the States have found out about this? I mean, with all this going on, why have none of the States taken action against physicians doing these sort of actions?

Mr. WEST. States have begun to take action. This is a relative—the provisions—the physician dispensing being promoted is a relatively new movement. In fact, within the last 2 years, it's a very new movement. So the States have moved to address this problem, and the FTC stepped in and stated that they were opposed to the activities.

Mr. BRUCE. And, Mr. Krahulec, you told me, in 22 States where there was activity against these avaricious, overprescribing, price-gouging, coercive physicians doing all these things, that in 22 States, activity just stopped because of one letter from the FTC?

Mr. KRAHULEC. No. I said "were in 22 States." I said that probably 8 of those were considering legislation late last year, similar to what Georgia had on the books.

Mr. BRUCE. I thought your testimony was, you said they're just dead.

Mr. KRAHULEC. Right now, because——

Mr. BRUCE. In spite of all this activity every day occurring in Georgia and Florida and Illinois and Montana, physicians overprescribing and having sodajerks in Kansas prescribe medicine, that nothing is happening in any of these States?

Mr. KRAHULEC. Part of the problem, of course, is developing the type of evidence you'd like to see. One of the questions is: Who is watching and enforcing whatever laws are on the books right now, many of which are inadequate?

In the State of New York, for instance, they have the Office of Professional Discipline that governs 31 licensed professions, including pharmacy. The medical profession has its own set of inspectors that are outside the purview of OPD.

One of the problems we've had is, who is enforcing? A lot of my testimony complained about the fact that some very necessary laws are enforced very heavily as to labeling, dating, just the fact that most statements don't even have a requirement that a doctor has to actually issue a physical piece of paper, but can make notes in the charts, which are often privileged. How do you go in and inspect for abuses, and problems like that?

A lot of the stuff that comes to us is anecdotal from our former customers who tell us, you know, that they couldn't get a prescription or they felt compelled to have it filled there because the doctor called out to the reception area and let the patient know it would be waiting for them as they left. This is the situation.

Mr. BRUCE. Well, Mr. Braden and Mr. Krahulec, given that situation, I mean, don't you know of any physician that might be concerned about medical malpractice where he just calls out to the physician's assistant or his nurse, "Give this person 3,000 capsules of Inderal," and send him on his way, "Pick it up on your way out?"

Is any physician you know of concerned about malpractice? I come from Illinois, and there are physicians there that have an ongoing concern about malpractice. I would think that medical records would be given, that a prescription would be signed by the physician. It would be given to a qualified individual within my office; if I were practicing medicine, I would make sure the dosage was appropriate, and the followup was done by myself or someone in my office.

Does that not occur in Georgia?

Mr. BRADEN. I do not know exactly what is occurring in those physicians' offices, because none of the regulators can go into those offices to see what's going on.

Mr. BRUCE. None at all?

Mr. BRADEN. No, sir.

Mr. BRUCE. Well, in the State of Illinois, we have a privilege situation, where there's legislation which I was—handle—and peer review which allows access of peer review organizations to review doctors' own records.

You do not have that in Georgia?

Mr. BRADEN. No, sir.

Mr. BRUCE. Not at all?

Mr. BRADEN. Well, we have similar situations of peer review in insurance settings and third-party payment settings, but those are—that's not the same thing as actually regulating the distribution of drugs.

Mr. BRUCE. So in a malpractice suit in Georgia. none of those records are available for anybody? The doctor just says, "None of this available?"

Mr. BRADEN. In the event of a malpractice suit, I'm sure subpoenas would be issued, and those records would be presented at that time. After the damage to the patient has occurred, presumably; we're talking about a suit.

Mr. BRUCE. Right. And has the Georgia legislature—I mean, how many suits have been brought against these physicians in Georgia, since that's your home State, for overprescribing, overcharging, having people who are unqualified give out—hand out medications as people drift by the door? How many charges have been——

Mr. BRADEN. I'm not aware of any yet and hope that none will occur, because I hope that no injuries will occur.

Mr. WYDEN. Would my colleague yield?

Mr. BRUCE. No. I just have 5 minutes.

So you're saying that no charges have been brought, but there is a serious problem in the State of Georgia with this kind of activity.

Mr. BRADEN. That's correct.

Mr. BRUCE. Unknown to the Georgia State Legislature.

Mr. BRADEN. The legislature was made aware of it, and the Georgia legislature enacted legislation giving the Board of Pharmacy the authority to regulate these activities, and the Federal Trade Commission stepped in and, for all practical purposes, threatened the members of the Board of Pharmacy with antitrust violations if they implemented the regulations which they had proposed. It's been a year now, and nothing's happened, and no enforcement of the law, and the business of selling drugs by doctors is growing extremely rapidly.

Mr. BRUCE. Could I have permission for 1 additional minute?

Mr. WAXMAN. Without objection, the gentleman is recognized for 1 additional minute.

Mr. BRUCE. Mr. Krahulec, just one question. Is there a chance in your mind that a doctor might, in fact, charge less than a pharmacist for any of these pharmaceuticals, given to him in prepackaged——

Mr. KRAHULEC. Sure.

Mr. BRUCE. So, I mean, there is a possibility that this is——

Mr. KRAHULEC. There's also a possibility that they would continue to distribute samples free of charge to the patient, which had until very recently been almost the sum total of their activity in the drug area.

It's only with the advent of the prepackage companies with the brochures that have been presented to you this morning that we've gotten into the broader-based, virtually no prescriptions——

Mr. BRUCE. But we might find in Illinois, for example, a single physician that would be willing to serve AARP recipients and sell at less than pharmacists' costs all these prepacked, widely used 50 drugs. I mean, that is a possibility.

Mr. KRAHULEC. It's a possibility.

Mr. BRUCE. OK. Thank you, Mr. Chairman.

Mr. WAXMAN. Mr. Bliley.

Mr. BLILEY. Thank you, Mr. Chairman.

Mr. Braden, you say this legislation is necessary to prevent unethical conduct by physicians.

Well, given that logic for a moment, should we not amend this legislation to apply to surgeons? I'll give you the case.

You go in to see the surgeon. The surgeon says, "Your gallbladder has got to come out, and I'm setting you up for 2 weeks from today at Hospital X," which he happens to be a part-owner of, as opposed to booking you across the street at the General Hospital where he also has privileges.

Couldn't we say surgeons shouldn't be able to send you to hospitals for procedures where they have a proprietary interest in the hospital?

Mr. BRADEN. I would say that the position that was articulated by the AMA earlier here, saying that the patient should be fully informed of the physician's financial involvement would be appropriate.

Mr. BLILEY. Well, I think that you are supposing that the judgmental factors of the patient of who's hurting are going to be better than what I would interpret it.

Mr. BRADEN. I agree.

Mr. BLILEY. But one other question, Mr. Braden, since it's not, I don't believe, clear in the legislation. Do you think that we should amend this so that the enforcement powers lie with the several States, to enforce this law, assuming it becomes law, or should we have the Federal Government enforce it?

Mr. BRADEN. It would appear to me—and I'm not an attorney, and I'm certainly not an authority in Federal/State legislation and how those things interrelate with each other, Mr. Bliley, but it would appear to me that, as a practical matter of enforcement, that would probably be an idea that certainly deserves consideration.

Mr. BLILEY. What deserves consideration?

Mr. BRADEN. The States enforcing the legislation.

Mr. BLILEY. OK. Thank you, Mr. Chairman.

Mr. WAXMAN. Thank you, Mr. Bliley.

Mr. Walgren.

Mr. WALGREN. Thank you, Mr. Chairman.

I wonder whether—you know, certainly some thought has to be given to whether or not the Federal Government should rush into this, and when you say that you'd like to see the States enforcing, but the Federal proscribing, why would that be? I mean, either the Federal ought to be doing it or not doing it.

Mr. BRADEN. Well, when the gentleman posed the question to me, I immediately started sitting here thinking of how do those things interact, and I thought about highway funds and so forth. As I say, I am not an expert in that area, and I don't understand exactly how those agencies, Federal and State agencies interact with each other.

But I do know that drug enforcement regulations and laws, the enforcement powers are transferred to State agencies under some type of contractual arrangement.

Mr. WALGREN. Let me ask you this. If I understand it, in some States, a doctor, to dispense, has to engage in some continuing education in pharmacy. If there were a real prospect that the Federal Government's getting into this to proscribe the profit would also have their prescriptions take whole cloth and override and preempt State laws that might require doctors to take continuing education in pharmacology, would that give you any pause as to whether or not you want the Federal Government occupying this field and defining in every sense exactly what the regulations of physicians in the area of pharmacy would be?

Mr. BRADEN. I think the legislation, as it has been posed, adequately covers the situation as it presently exists.

Mr. WALGREN. Would you have any pause if, by passing that legislation, you created a good legal argument that a number of other State restrictions on physicians should therefore fall?

Mr. BRADEN. If it indeed created that argument, yes, there would be reason to pause.

Mr. WALGREN. It would give you pause.

You mentioned, Mr. Braden, that there was an absence of regulatory authority on the State level to catch up with this repacking phenomenon.

Mr. BRADEN. That's correct.

Mr. WALGREN. What is that absence? Can they not proscribe doctors from dispensing?

Mr. BRADEN. No, sir. The problem is that we have medical laws on the books and pharmacy laws on the books, and pharmacy laws—all laws and regulations in Georgia and, I assume, in virtually every other State, which pertain to the distribution of drugs and the accountability of drugs—and there are several issues, of course, that we have not discussed here today, such as the myriad of laws and regulations which have been enacted by Congress and the Drug Enforcement Administration to put controls on the distribution and accountability of controlled substances—all of those laws are found in various code sections at the State level dealing with pharmacy. And in those same code sections is the authority for Boards of Pharmacy to enforce and regulate those laws, and then depending on the various States, the Boards of Pharmacy interact with some law enforcement agency within the States for the purpose of enforcing that code section.

But with medicine, they cannot do that.

Mr. WALGREN. But they would have the authority. The authority may not be presently exercised or implemented or even created, but States do have the ability to create the authority to pass almost any regulation relating to physicians prescribing drugs, do they not?

Mr. BRADEN. Sure. The States have the ability to enact legislation.

Mr. WALGREN. I get troubled by the idea that there seems to be a "whose ox is being gored" phenomenon here, where the pharmacists obviously have an interest to protect, and the physicians may have an interest to protect.

Why has this come on so suddenly? Someone said it's been only 2 years. What's been the change in circumstances in those 2 years that has created the impending explosion of this kind of dispensation?

Let me give you a short answer. Is it physicians being squeezed for their income, or is it something else that has brought this on?

Mr. BRADEN. It's something else. In my opinion, repackagers are now marketing to physicians that they can——

Mr. WALGREN. What's enabled them to do that? Why is this happening in these 2 years, and it didn't happen 10 years ago?

Mr. BRADEN. There was nothing—no State laws on the books to preclude this, so therefore——

Mr. WALGREN. But there were not—oh, this was precluded by law 10 years ago?

Mr. BRADEN. No, no, no. It is not precluded, never has been precluded.

Mr. WALGREN. But what is it that's bringing this on? That's my question.

Mr. KRAHULEC. If I may, I think it is clearly a dollar issue. Take hospitals, for instance. The Federal DRG's and other cost-containment efforts have put a cash squeeze on many hospitals. We have hospitals in Central Pennsylvania that are putting dispensing clinics in all their rural doctors' offices, where they wouldn't have touched them 5 years ago, because with the money they were able

to generate through the uncontested billings, OK, they didn't need the additional profit center.

Now with the appendectomy being restricted, they're looking for every dollar of cashflow they can, and they're getting into related areas. But there are no concurrent checks and balances in the State laws to watch the labeling and the storage.

Mr. WALGREN. If I might make one other point or question, Mr. Chairman, the thing that troubles me is that I see the pharmacists trying to take advantage of economies of scale by mass pharmacy services, where now I have no contact with a pharmacist anymore. When I go to the large chain drugstore, I am handed that prescription by a clerk in every estimation, and there is somebody back there who is counting or somebody back there who is packaging, but I never see them.

And it seems to me that the retail pharmacy people have, in order to take advantage of these economies of scale, withdrawn that pharmacist from the contact with me. And yet at the same time, I see you arguing that another point in this process should not have the ability to use those same new economies of scale that are apparently available.

And I would like to ask you, as retail pharmacists, what have you been doing to maintain the contact of the pharmacist with the individual patient that is coming in to have his prescription filled? And in my experience, it has been—the pharmacist has been removed from contact with the individual patient because of the economies of scale that the large chain drugstores have been putting in place over these several years.

Is there something that you, as pharmacists, have been doing to keep the pharmacist in personal contact with the patient?

Mr. WAXMAN. The gentleman's time has expired. Could we just have a very brief answer to that question?

Mr. WEST. Congressman, our members, the independent retail pharmacists, we've prided ourselves for years that the independent does provide the service, the counseling, and the comprehensive pharmaceutical services. The important thing here is on this issue, with physician dispensing, the patient does not have a choice, pure and simple.

Mr. WAXMAN. Thank you, Mr. Walgren.

Gentlemen, we appreciate your testimony. It's been very helpful to us as we think through this issue before us.

Our final panel includes a representative of the drug repackaging industry, Mr. Charles A. Hampton, chairman of Allscrips Pharmaceuticals; Dr. Robert Taylor, president of the American Academy of Family Physicians; Dr. Richard Fields, president of the Medical Society of Virginia; and Dr. Michael Weinstein, a pediatrician from Fort Valley, GA.

We are pleased to welcome you to our subcommittee hearing. Your prepared statements will be in the record in full. We will ask you to restrict your summary of that statement to no more than 5 minutes.

Why don't we start with you, Mr. Hampton.

STATEMENTS OF CHARLES A. HAMPTON, ON BEHALF OF COMPETITIVE HEALTH CARE COALITION; ROBERT H. TAYLOR, PRESIDENT, AMERICAN ACADEMY OF FAMILY PHYSICIANS; RICHARD L. FIELDS, PRESIDENT, MEDICAL SOCIETY OF VIRGINIA; AND MICHAEL P. WEINSTEIN, PEDIATRICIAN, FORT VALLEY, GA

Mr. HAMPTON. Thank you, Mr. Chairman, for the opportunity to appear today before your subcommittee. My name is Chuck Hampton.

During yesterday's hearings, you expressed concern over the fact that drug prices are continuing to increase dramatically. I suggest that both the markups by manufacturers and by retailers should be examined. Both can contribute significantly to cost reductions. Retail stores currently have no real competitors, but physician dispensing is beginning to compete, and I am here solely to address that issue.

I am testifying for the Competitive Health Care Coalition, a group of new companies referred to as drug repackagers. More accurately, we are national pharmacies providing very high quality prepackaged prescriptions to physicians for direct dispensing. I am president of Allscrip Pharmaceuticals. I have 29 years of drug industry experience, and I am very familiar with drug pricing.

I will explain how we are benefiting the American consumer. First, we offer clear, quality benefits in packaging integrity, clean, dedicated packaging environments, and multiple quality assurance checks on all prescriptions. Unlike 25 years ago, today's physician dispensers do not just count pills and slip them into an envelope. When the physician dispenses our prepackaged product, he utilizes a complete pharmacy system, including full warning labels, tamper-evident sealed containers with built-in dispensing records. The doctor merely adds the patient's name and special instructions to the label.

Unlike variety store pharmacists with uncontrolled packaging environments, we operate under the stringent good manufacturing and control practices regulated by the FDA and the DEA. Also unlike drug stores, our system allows lot number tracking from the manufacturer to specific consumers.

The real issue of this bill is economics and competition. When competition is allowed to work, it results in higher quality and lower prices. By increasing competition at the manufacturer's level, the Waxman-Hatch Act made generic medications widely available. Now we need competition at the retail level as well because the potential savings on many generic drugs have not been passed on by retail stores to consumers.

Prior to dispensing prescription drugs, the typical physician never really looked at a drug price list. Once personally involved, we find doctors eager to save their patients money. Our firms report that as much as 80 percent of their sales are in generic products.

Doctors are finally able to evaluate the real cost to benefit of both new and old brand drugs and the savings possible with generics. Mr. Chairman, this is key. If we are to begin lowering con-

sumer drug prices, doctors must become involved in evaluating the costs of the drugs they prescribe in addition to safety and efficacy.

Our system will reduce drug costs even further. A drug store pharmacist following the antiquated traditional procedure of hand-counting and labeling 100 individual prescriptions today results in a $2 per prescription cost. One of our pharmacists using high speed packaging machinery can package 1,000 prescriptions a day at a cost of 10 cents.

Proponents of this legislation theorize that physicians will overcharge. Our actual experience is quite the contrary. Physicians are very sensitive to the effect improper dispensing could have on their community relations. They are also very conscious of their patients' total bill. Doctors also don't want a $50 drug charge on top of a $30 office visit. Their average $3 gross markup on a prescription is not worth the risk of losing a patient.

As already mentioned several times, this illustration shows physicians constantly choose many in-office patient services like throat cultures, blood work and xrays. Prescription drug dispensing is just one more service fee provided for profit. Physicians have long been managing these ethical considerations.

To assure ourselves, we consulted with Dr. Lawrence McCella, Associate Professor of Community and Family Medicine at Georgetown University, and senior research scholar of the Kennedy Institute of Ethics. Dr. McCella has assured us that while ethical issues are present, it is no less manageable than the others that I have described. He is with me today to answer any questions.

Proponents of this legislation suggest that physicians should not dispense for profit, but without profit, there obviously would be no new competition for drug stores. This graph compares the drug store versus physician prices based upon a recent informal survey. Hands down, the physician prices were substantially lower. Proponents of this legislation theorize that the psychology of the physician-patient relationship provides a captive market. We have no evidence of this.

Location does give doctors a competitive advantage, but a competitive advantage does not equate to anti-competitive. Parents of small children, working mothers, the elderly and many sick or injured patients simply want to avoid the extra trip to the drug store.

[Testimony resumes on p. 140.]

[The prepared statement of Mr. Hampton follows:]

HEARINGS BEFORE THE SUBCOMMITTEE
ON HEALTH & THE ENVIRONMENT, COMMITTEE
ON ENERGY AND COMMERCE, U.S. HOUSE OF
REPRESENTATIVES, APRIL 22, 1987, ON

H.R. 2093

STATEMENT OF CHARLES A. HAMPTON ON BEHALF OF
THE COMPETITIVE HEALTH CARE COALITION

Mr. Chairman, thank you for the opportunity to appear before the Subcommittee today. My name is Chuck Hampton. I am chief executive officer of Allscripe Pharmaceuticals, Inc., of Vernon Hills, Illinois. Allscripe is a pharmaceutical company engaged in a relatively new business which has come to be known as drug repackaging. We are actually a national pharmacy which provides very high quality prepackaged prescriptions to physicians for direct distribution to their patients. I am testifying here today on behalf of the Competitive Health Care Coalition, a group of similar companies organized for the sole purpose of opposing H.R. 2093.

We named our group as we did because our industry has begun to introduce new competition into one of the last segments of the health care delivery system in which virtually none has existed -- the retail distribution of prescription drugs. The bill under consideration would eliminate that competition. It would also eliminate our repackaging industry. Astonishingly, it would do so at the urging of the very industry with which we are trying to compete and which has labelled our efforts as "anticompetitive" -- the $30 billion retail prescription drug industry.

We have introduced competition into this business by providing to physicians an innovative, safe and efficient total system by which they can offer to their patients the choice of taking a prescription to the drugstore or obtaining the prescribed drug directly from the physician during the office visit. Our system offers all prescription drugs, prepackaged and ready for the patient, as well as integrated recordkeeping, lockable storage cabinet and pricing recommendations. The physician usually selects the 25 to 50 prescriptions most commonly used in his or her treatment regimen. The patient is not deprived of selection, as the drugs dispensed are exactly the same as those that would otherwise have been subject of a written prescription for the drugstore. Written prescriptions are utilized for refills and for the occasional indicated medication not stocked by the physician.

Our pharmacists provide the physician with the drugs already in the safety-sealed, labelled container ready for the patient. The physician does not become a pharmacist in any sense; he merely adds the patient's name and any special instructions to the label and hands the unopened container to the patient. The physician is thus able to add a new dimension to the service he or she provides; the patient who chooses to utilize the service avoids the time and inconvenience of an additional trip to the drugstore; and everyone utilizing the system is delighted. Indeed, the only complaints we have heard are those of the retail drugstores.

I firmly believe that the real issue presented by this bill is the economic one -- whether physicians should be allowed to compete with drugstores. Nevertheless, other issues have been raised, and I shall address them. On the merits, I think you will resolve each of them in favor of competition and against the bill.

Competition. The notion that competition will lead to efficiency and low prices has long been fundamental to our legal and economic systems. This Committee is acutely aware of the continuing need for lower prices in our health care system. Various legislative policies in recent years have recognized the relationship between competition and cost and have generally tended to stimulate or even mandate, rather than restrict, innovative approaches challenging the traditional delivery system.

Although representing a significant portion of the nation's health care bill, the retail prescription drug distribution system has received relatively little attention. The 1984 Waxman-Hatch Act paved the way for the first significant drug price reductions by making quality generic medications widely available at substantially reduced prices resulting from fierce competition at the manufacturing level. Unfortunately, its goal was only partially achieved, as the retail drugstores decided to pass only part of their cost savings on to consumers. In many instances they have actually increased their profit margins for generics over those maintained for comparable brand products. This is why most retail

drugstores promote generics.

I believe that physician dispensing will help to complete the job the 1984 legislation set out to do. The firms in our industry report that as much as 80% of their sales to physicians are generics. We find that many physicians have not previously prescribed generics because they were unaware of the true cost difference and tended not to trust their quality. Once they become personally involved and are assured of a consistent source of quality, the physicians are eager to save their patients money. One does not have to be an economist to appreciate that the drugstores, if they cannot convince this Congress to prohibit physician dispensing, will have to compete for the patient's prescription dollar and might just find reduced profit margins an effective way to do so. Allowing physician dispensing to continue can only lead to lower prices, based solely upon the fundamental principle of competition.

There are other reasons why our system will reduce drug costs. It is more efficient. A $40,000-a-year retail pharmacist hand counting and labelling 100 individual prescriptions a day results in a pharmacy labor cost of $1.50 to $2.00 per prescription. Our pharmacists, even at this stage of our development, can prepare some 1,000 prescriptions daily, using high-speed machinery, resulting in a pharmacy labor cost under ten cents per prescription. With a larger customer base, and resulting larger runs of individual drugs, that cost will be reduced even more.

Right now the annual sales volume of our entire industry is about $30 million. If we are to be allowed to grow to, say, $1 billion, we will then be about half the size of the retail drugstores' tobacco sales. More important, though, many of us will then have the buying power to lower our costs even further.

There seems to be a popular notion that physicians, given the opportunity to sell prescription drugs to their patients, will, as a profession, have the tendency to overcharge. Our experience shows otherwise. We find our physician customers to be quite sensitive to their image in their patients' eyes and eager to have us insure that they will not be embarrassed by their prices. Physicians operate in an increasingly competitive environment and are already quite conscious of the level of their overall charge to the patient. They are not inclined to exacerbate the matter by an unreasonable prescription drug charge. The average $3 gross markup they might receive for a prescription drug is simply not worth the loss of a patient who might go to the drugstore for a refill and discover the store to be charging significantly less for the same thing.

We frequently hear of patients checking drugstore prices after receiving a prescription drug from their physician. Physicians are very much aware that the patient who finds a significantly lower drugstore price will return with a complaint on the next visit -- if he or she returns at all.

I might add, parenthetically, that our physicians need our help in establishing competitive pricing, for neither they nor the consuming public have any real way of knowing what the drugstore charges for the vast majority of prescription drugs they sell. Except for the high-volume "loss leader" drugs, the consumer in most cases learns the price when she reaches the checkout counter. The physician writing the prescriptions generally never learns what the patient ended up paying at the drugstore.

We have the time, and, of course, the motivation, to be able to tell our physician customers what the drugstores are generally charging in their communities for the drugs they will be dispensing. We can also provide them with national price survey data. We find that our physicians, in general, are basing their prices upon those charged by the major chains and most often are charging less. As most of you are probably aware, the chains are usually significantly lower than the small independents.

In some communities the difference between the physician's price and the chains' can be rather significant. One of our members, for example, just last Tuesday conducted an informal survey in the Los Angeles market and found the price charged for a particular drug (PEN VK 250mg #28) by the same drugstore chain on the same day to vary from $5.57 to $6.45 to $7.63 within three different sections of the city. The lowest price was found in its suburban Orange county outlet; the

highest in the low-income Watts area. A dispensing physician serving patients in Watts and following our suggested pricing would be in a position to effect considerable savings for his patients. Again, one need not be an economist to predict that several dispensing physicians in the neighborhood of that retail outlet would quickly bring about a change in its pricing policy. This, too, has been our experience.

Our members have also found that while the opportunity to increase their income is attractive to some physicians, an important incentive to many who are interested in dispensing drugs is its value in enabling them to compete more effectively with the ever-increasing array of "full service" providers. The ability to avoid an extra trip to a drugstore is a tremendous convenience to many patients, particularly the elderly, parents of small children, and those who are injured or are just too ill to do anything but go home and rest. A recent survey by the National Association for Ambulatory Care showed that patient convenience was the principal motivation for their members in deciding to dispense drugs.

And on the subject of increasing physicians' income, it is sometimes suggested that physicians, unlike businessmen, pharmacists, lawyers and other professionals, should not be interested in making money. But the profit motive is still fundamental to our free enterprise system, and I believe it has been instrumental in delivering more efficient, cost-effective health care to consumers. One area in which this

has occurred has been the increasing trend toward performing on an outpatient basis more and more surgical procedures that formerly consumed several inpatient hospital days. While technological advancement has had a lot to do with this trend, I think it highly unlikely that it would have been so dramatic had Congress told the outpatient providers that they were not to earn any profit in performing these procedures. There is no valid reason why the profit motive, here in the form of a prescription dispensing fee, should not similarly be allowed to bring new competition into the retail drug distribution market.

I have heard voiced a concern that physicians, because of the psychology of the physician-patient relationship, do not offer patients a true choice but really have a captive market. This is apparantly the basis for the drugstores' claim that physician dispensing is anticompetitive. To be sure, the physician has some competitive advantages over the drugstore. The patient can discuss the medication with the physician as she is receiving it and in the privacy of the physician's office. There is the substantial convenience of which I have spoken, and location has long been recognized as a strong competitive factor in retail markets. There is usually a price advantage. Some patients may wish simply not to offend their physician by revealing a preference for the drugstore.

But these possible advantages are no different from the competitve advantages found in all segments of the economy. A competitive advantage does not equate to "anticompetitive."

If the competitive advantage is somehow abused -- as by forcing the customer to accept poor quality or unreasonable prices -- there may be cause for concern. And if the concern is justified, it may be appropriate to prevent the abuse. But first, I would hope that you would require some actual evidence of abuse. As I have said, our data show that dispensing physicians are charging less than even the large chains for most prescription drugs. If the data were otherwise, however, and physicians were charging unreasonable prices, legislation regulating retail drug prices might well be called for. It is not called for in the absence of any credible evidence of overcharging or any other abuse.

Quality. Quality is an area in which our industry offers clear benefits in terms of quality assurance checks, package integrity and security, and the environment in which packaging occurs. Physician dispensing today is not the physician of 25 years ago slipping a handful of pills into an envelope. We supply the drug, with full warning label, already in its tamper-evident sealed container. The physician merely furnishes it, unopened, to the patient. The companies who prepare the drugs for the physician operate under the stringent regulations and guidelines of the FDA and DEA. Repackagers themselves employ licensed pharmacists. Plant personnel are not subject to the distractions and pressures familiar to the pharmacist in today's variety store/supermarket/pharmacy where prescription filling is not separated

from store traffic, is subject to air contamination, is frequently accomplished with unclean counting devices and is not subject to checks to insure that the prescription has been correctly filled.

Our system provides lot number tracking from the original manufacturer to the consumer. I am not aware that tracking is possible beyond the drugstore in the traditional distribution system. In many cases the lot number cannot be traced beyond the wholesaler in case of a manufacturers' recall. In contrast, we can pinpoint each patient who might have the recalled drug.

While I have not yet heard criticism of our industry's product from a quality standpoint, I have heard a quality-related argument that physician dispensing eliminates valuable "checks and balances" inherent in the drugstore distribution system. As I understand it, this is a reference to the fact that drugstore pharmacists occasionnally discover and correct prescribing errors by physicians. While most of those are harmless communication errors, an occasional harmful error undoubtedly occurs. By the same token, it cannot be denied that drugstore pharmacists have occasionally dispensed a drug other than the one prescribed by physician. Although physician dispensing eliminates [illegible]bility of such pharmacist error, we do not advoc[illegible]mination of the retail drugstore.

It has been documented that a significant number of patients never have the prescription given by their doctor

filled, or wait several days before having it filled. Patients are far more likely to use the medication prescribed when the physician is also the dispenser. And while the physician cannot know what happens after the patient leaves the office, the physician at least knows that the patient has obtained the drug or has informed the physician that he or she will not or might not take the drug.

Ethics. I believe that most will agree that physician dispensing of pharmaceuticals poses a potential ethical problem. Will the physician's financial interest in selling the drugs color his judgment in serving the best interests of his patient? This is a legitimate question, and is the same question presented by virtually every facet of the traditional fee-for-service health care delivery system. Will the physician or dentist with his own x-ray equipment overexpose patients to its harmful effects? Will the surgeon perform unnecessary, life-threatening procedures? Will the physician maintaining her in-house lab facility perform needless tests, or perform only those tests of which her lab is capable of performing? Will the pediatrician instruct the mother to bring the sick child back for a second, needless $30 office visit?

In fact, this same ethical question is posed today in virtually every aspect of our cost-conscious health care delivery system. Will DRG-based reimbursement cause a hospital to discharge a patient prematurely? Will the capitated HMO physician spend enough time with the patient to discover

the nature of the illness? Perhaps some will not, and perhaps some fee-for-service practitioners will overutilize or be tempted to engage in other abuses designed only to line their pockets. But I am not aware of any serious legislative proposal to ban HMOs or physicians' furnishing and charging for x-rays, throat cultures, or EKGs. If there are abuses, they should by all means be corrected -- through peer review, state licensure procedures or even legislation if necessary. The notion that dispensing of drugs for profit should be placed in some special category of outright prohibition on ethical grounds, however, is truly an extraordinary one and would be incomprehensible to me were it not for the extensive retail drugstore lobby.

The Competitive Health Care Coalition has consulted with an expert on medical ethics to be certain that we had not overlooked some unique problem inherent in the dispensing of pharmaceuticals. He assured us that we had not, confirmed that the ethical problem is certainly present, but believed it to be no less manageable than the others that I have described.

I do not know whether the retail druggists have their own code of ethics. If they do, I wonder what it says about the standard half-hour wait for the prescription while consumers are provided a single chair or no place at all to sit and are left to browse through the vast array of goods on display. Why is the prescription counter always in the rear of the store? Does their code suggest a need to disclose the prices

and quality levels of the generic drugs that are sold? And more to the point, I wonder if the Florida druggists are concerned about their own temptation to overprescribe or misprescribe now that they are permitted to prescribe drugs. Their desire for federal control of physicians' ethics is admirable, but there has been shown absolutely no need for such control.

* * *

I think it is clear that if physician dispensing had any significant negative aspects for the consuming public we would not be before this Committee today. Rather than making this special-interest legislation their number-one priority, the members of the National Association of Retail Druggists would expose those negatives to the public. They would compete. They know, as well as you and I know, how effective competition can be in combating low quality, poor service or high price. They know very well, and that is why we are here. I urge you to reject this bill and to allow us and the physicians to compete with the drugstore industry.

I appreciate the opportunity to have appeared before this Committee and would be pleased to answer any questions you may have.

Mr. WAXMAN. Dr. Taylor.

STATEMENT OF ROBERT H. TAYLOR

Mr. TAYLOR. Mr. Chairman, I am Robert H. Taylor. I am president of the American Academy of Family Physicians, and on behalf of our some 59,000 members, I would like to appear before you today to give some of the Academy's thoughts on the issue of physician dispensing.

Family practice is a comprehensive specialty. The family physician assumes the responsibility for the total health care of the individual and the family, taking into account various dimensions of that care. Integral to family practice is the knowledge of the use of drugs and their interactions, and patient education and counseling regarding medications is a part of the service that family physicians normally render. These skills are taught in residency programs and also in our continuing education courses.

As a service to patients, some of our family physicians do choose to dispense prescription drugs from their offices. The official position of the American Academy of Family Physicians on the issue of dispensing was adopted by this organization's 1986 Congress of Delegates, and I will share that with you.

"The American Academy of Family Physicians believes that physicians have the right to diagnose, prescribe for and dispense therapy wherever and whenever it is appropriate. The Academy believes that no regulation or law should infringe upon that right. The Academy believes that physicians dispensing therapy should be held to the same high standards as other professionals so privileged." I would point that out.

Mr. Chairman, the rest of my prepared testimony will be in your materials, and I would like to just make a few comments as we go along. Now, it is not appropriate, really, and you have heard this many times today, for the Congress to restrict medical practice since this has traditionally been a State responsibility. The Academy seconds those other people who have made the same point.

The prescribing and dispensing of prescribed drugs is consistent with the present Food, Drug and Cosmetic Act. Also, family physicians coordinate the total health care of the patients, and therefore they are quite familiar with all of the prescription medications that a patient is taking, and therefore, harmful interactions are diminished in their occurrence.

Family physicians—and I have talked to some and we have queried others—dispense the prescriptions which they prescribe most and that they are most familiar with. These prescriptions tend to be for acute care. The prescriptions are generally dispensed at a decreased cost over that identified at local pharmacies.

Also, the reason for the dispensing primarily is that of convenience for the patients and providing a better-coordinated care for the patients.

Now, as we look at those things, I have heard a number of issues raised this afternoon, and I would like to point out several.

The business of price gouging. In my duty as president of our organization, I have traveled this country from coast to coast, and in the last 2 years I have been in most of your States. I can tell you

with the family physicians the business of dispensing is really not a major issue. It only becomes an issue when present services are not adequately available to take care of their patients. It is not a price center with any physician with whom I have talked.

Overprescribing and the business of ethical conflict. We are inundated with ethical conflicts. Somebody mentioned HMO's. I have trouble finding anything much more ethically challenging than the business of providing less care in order to make more money at the end of the year. We are inundated with them, and with all the wisdom in Washington, I doubt that you folks can solve our ethical problems with legislation. This still is a State issue of dispensing.

Then the business of profit. Can you really believe that physicians are just a sucker for every high pressure salesman that comes down the road? I have run more than one out of my office within the last month. We are not that naive. We look at all the issues very carefully, including that of generic prescribing. Some generics are quite good; others we have questions about, and if we are not comfortable with them, we don't use them. The same would be true for anybody that comes down to sell us medications who says this can make you a pile of money, all you have to do is prescribe 100 prescriptions a day for the next 100 years. We know all those games, and we don't play.

[The prepared statement of Mr. Taylor follows:]

TESTIMONY OF AMERICAN ACADEMY OF FAMILY PHYSICIANS

Mr. Chairman, I am Robert H. Taylor, M.D., President of the American Academy of Family Physicians. On behalf of our more than 59,000 members, I am pleased to appear before you today to share our thoughts on the practice of physician dispensing of drugs.

Family practice is a comprehensive specialty. The family physician assumes the responsibility for the total health care of the individual and family, taking into account the social, physiological, economic, cultural and biologic dimensions. Integral to family practice is the knowledge of the use of drugs and their interactions, and patient education and counseling with respect to medications. These skills are taught in each accredited family practice residency program and in AAFP continuing education programs.

As a service to their patients, some family physicians choose to dispense prescription drugs from their offices.

The official position of the American Academy of Family Physicians on the issue of physician dispensing was adopted by this organization's 1986 Congress of Delegates. The policy statement reads as follows:

The American Academy of Family Physicians believes that physicians have the right to diagnose, prescribe for and dispense therapy whenever and wherever it is appropriate. While the Academy believes that no regulation or laws should infringe upon that right, the Academy believes that physicians dispensing therapies should be held to the same high standards as other professionals so privileged.

The American Academy of Family Physicians does not believe that it is appropriate for Congress to restrict physician practice, which traditionally has been a responsibility of States through licensing mechanisms. The prescribing and dispensing of approved drugs by licensed physicians is consistent with the Food, Drug and Cosmetic Act.

As patients' personal physicians who coordinate total health care delivery, family physicians are familiar with their patients' medical histories, and know whether they are taking medications prescribed either by themselves or by other physicians to whom the family physicians may have referred the patients. The opportunities for harmful drug interactions are reduced because physicians are aware of the medications taken by their patients.

In preparing for this hearing, we have talked with several of our members who dispense medications in their offices. I would like to share with you some examples of the dispensing practices of these family physicians which I believe will answer many of the questions that you may have.

The family physicians we interviewed dispense between 20 and 40 medications. The products that they stock reflect their individual prescribing practices, and tend to be a combination of both brand and generic drugs. In most instances these a.e drugs for acute conditions, such as antibiotics, as opposed to those drugs for the treatment of chronic conditions.

The physicians do offer their patients the option of having the prescription dispensed either at a pharmacy or in their offices, but report that most patients like the convenience of receiving the medication prior to leaving the physician's office. This is particularly important to the parents of small children who are sick; as for example, the crying child with an ear infection requiring antibiotics. Rather than having to take the child from the physician's office to the pharmacy and wait for the prescription to be filled, the parent can immediately obtain the medication from the physician and take the child home. Dispensing can also be very convenient for patients at times when medication is needed and a pharmacy may not be open or readily available. The patients receive the same medication they would from the pharmacy, including generic medications, because physicians tend to stock the drugs that they prescribe.

The physicians we spoke with also provide these medications at a lower price relative to pharmacies in their areas. In fact, many of the physicians expressed surprise when they learned about the low cost of some medications relative to what pharmacies generally charge. Consequently, even after a handling mark up by physicians, the price paid by patients for medications dispensed by family physicians may be substantially less than those dispensed from pharmacies. At a time when the Federal Government is concerned about health care costs, physician dispensing may provide a cost-effective alternative for patients.

Physicians report that patients are very satisfied with the quality, price and convenience of medications dispensed from the physician's office.

The Academy of Family Physicians is concerned that prohibitions or restrictions on physician dispensing would be detrimental to those patients whose family physicians currently offer the convenience and cost effectiveness of dispensing medications. We are particularly troubled that such a prohibition is being considered in the absence of evidence that physician dispensing has been harmful to patients, either medically or financially. Frankly, in today's competitive world of medicine, the patient dissatisfied with either the quality or cost of medical care will find another physician. We do not believe that physician dispensing has resulted in such patient dissatisfaction. On the contrary, family physicians report that patients, in subsequent visits, ask for medications to be dispensed from the office.

To prohibit physician dispensing would impose an inappropriate Federal restriction on the practice of medicine, ultimately hurting patients. The American Academy of Family Physicians urges the subcommittee to oppose such a prohibition.

Thank you for your attention to our concerns. I would be pleased to answer any questions at this time.

Mr. WAXMAN. Thank you very much, Dr. Taylor.

Mr. TAYLOR. Thank you.

Mr. WAXMAN. We appreciate that testimony.

Dr. Fields.

STATEMENT OF RICHARD L. FIELDS

Mr. RICHARD FIELDS. Thank you, Mr. Chairman.

Mr. Chairman, members of the committee, I am pleased to appear before you here today to address the issue of physicians dispensing drugs from their offices. I can also tell you that this will probably be the briefest testimony you will have received this afternoon.

My name is Richard Fields. I am an otolaryngologist from Fairfax County, Virginia, and I am currently serving as the President of the Medical Society of Virginia. The society is an organization of 6,000 physicians throughout the State. Until we meet in executive committee this Friday, we will not have an official policy on this issue, but we do expect to discuss it at that time. However, I be-

lieve I can state that my feelings represent those of most physicians in the Commonwealth.

We are discussing here the issue of physicians dispensing drugs from their office for profit. While I believe that it is certainly proper for a physician to give a patient drug samples to get them started on medication until they have a prescription filled or in other situations, I definitely oppose, for safety and ethical reasons, physicians selling prescription drugs from the office.

Our first and foremost concern should be, as it always should be, the protection and welfare of the patient. While most physicians are ethical people, it is unlikely that the physician would be able to stock the wide variety of drugs kept by a pharmacy. Consequently, the temptation would be for a physician to prescribe or dispense the drug he has in stock, which might be almost as good rather than that which is best for the patient or the ailment at that time.

Second, I believe that a good check and balance system now exists between physician and pharmacist, a relationship that has existed for many years, which would be absent were physicians to sell drugs from their offices. As the system now works in Virginia, the pharmacist calls the physician if there is any conflict with other drugs the patient may be taking, either through the same physician or through other physicians, and the pharmacies have that on record, usually, in their computer systems.

The pharmacist can also call the physician if he feels there may be some question about the appropriateness of the prescription or the dosage, and I think any caring physician would not resent a pharmacist serving as that check on his care of his patients. Thus, the pharmacist serves, in my opinion, as a backup for errors and abuse.

The third reason is one of physician recordkeeping. The recordkeeping required to maintain prescription drugs, some of which may be controlled substances, would be cumbersome and an added burden to what is already an overwhelming amount of paperwork required to run a physician's office today, and as a private practitioner, I simply would not want to have to add that to my staff's work.

There are two instances in which I consider the dispensing by a physician for profit to be acceptable. The first is in the case of a physician located in a geographical area where a pharmacy is not available. The second would be when a patient is seen on a holiday or at night when the pharmacy is not open or available and which medication is needed immediately.

Virginia law prohibits physicians from selling prescription drugs for their own convenience, for the purpose of supplementing their own incomes, or to individuals who are not their patients. Our State Board of Medicine will be holding hearings on this very issue on May 2 to examine alternatives or means of strengthening this law. They will be making recommendations to the General Assembly of Virginia in 1988.

While I firmly believe that the selling of drugs by physicians from their offices for profit or otherwise is not ethical and should not be done. I also firmly believe it should be decided at the State and not the National level because such laws integrally affect the practice of medicine. However, should Congress decide to pass such

legislation, I hope you will mandate that the guidelines be administered at the State level through mechanisms that are already in place, such as the State boards of medicine or health regulatory boards.

In closing, I am honored to have the opportunity to state my views to this body which plays such a very large role in the way the American health care system is evolving, and this concludes my formal remarks. I will be happy to answer any questions.

Thank you very much.

Mr. WAXMAN. Thank you very much.

Mr. Weinstein.

STATEMENT OF MICHAEL P. WEINSTEIN

Mr. WEINSTEIN. Mr. Chairman, members of the subcommittee, thank you for allowing me to speak before you today. I am Michael Weinstein. I am a pediatrician from Fort Valley, Georgia, which is one of those small communities in a largely rural area, which presumably questions of physician dispensing may be addressed to.

I am in the private practice of pediatrics, and I'm the Chief of Pediatrics at the Peach County, Hospital in Fort Valley. In addition, I write a weekly medical column for the Macon, Georgia Telegraph and News, whose topics vary from medical advice to medical politics.

The article I wrote for the October 15, 1986 issue of the Macon Telegraph opposed the physician dispensing of drugs. Apparently, it is the dissemination of this article in areas wider than middle Georgia that has allowed me to be here today.

There are many extrinsic challenges to medical excellence, and they come from government, industry, and the insurance industry in particular. I don't think we need a challenge from within to further endanger the excellence in the practice of medicine, and I believe that physician dispensing of drugs is such a challenge.

I think it's best that I just summarize the six points that I addressed in my original article.

Number one, physicians dispensing their own drugs have a limited formulary and will be pressured economically to dispense the drugs they stock, although others might be better or cheaper, and perhaps to dispense a drug about to go out of date when others might similarly be more appropriate. When the person prescribing the drug also benefits financially from selling it, there is no check and balance on the procedure. A physician prescribes a drug by writing a prescription and has no financial interest in what that drug is. The pharmacist who fills that prescription and makes the financial benefit has no choice in what that drug is, except within the limited State generic substitution laws.

Number two, it may be convenient for a patient initially to avoid going to a pharmacy to fill a prescription, but it is not in the patient's interest to return to the office for every refill. First, physicians' offices are not open as long as pharmacies are. Second, there is a suggestion from some areas that physicians are collecting office fees for every refill revisit, something that does not occur in an ordinary trip to the pharmacy. Under any circumstances, patients

will find it far less convenient to get their refills at the doctor's office than at the drugstore.

Number three, the argument that physician dispensing is necessary for after-hours treatment is specious. In my small community, there are two pharmacies open seven days a week, and at least three of the private pharmacists will come out at any hour on any day to open up the pharmacy to dispense drugs for their patients. In large cities, there are usually stores open late or even all night. Physicians have traditionally had samples provided free by the pharmaceutical companies and which they give free to their patients as starter doses until pharmacies are open the next morning. Most of the pharmacies in my area will deliver, so that patients who are unable to make the trip to the pharmacy are at no disadvantage.

Number four, regardless of intentions, physicians cannot take time that would otherwise be profitable seeing patients to dispense drugs at a small markup. Either the system will fail to work, or the doctor will inevitably charge higher and higher markups to pay for his or her time.

Number five, if all or even a significant number of doctors dispense from their offices and skim the most common or most profitable drugs, many pharmacies could not stay in business to provide the uncommon drugs, which we all must write from time to time, but which no physician could afford to stock in an office formulary.

And finally, I do not believe that medical services—that is, diagnosis and treatment—should be provided by anyone other than physicians, and conversely I do not believe that physicians should provide non-medical services. I believe that the diagnosis and treatment of disease should be the responsibility solely of the physician, and conversely that this should be the sole responsibility of the physician.

My interest in coming here is to be an advocate for the interest of my patients, and I feel that my patients' interests are best served with an independent physician and pharmacy corps, and that the physician dispensing trend will inexorably lead to a deterioration of medical quality through the loss of the currently excellent channels for distribution of all drugs and to the demeaning of medicine as a profession.

Thank you for your time.

[The prepared statement of Mr. Weinstein follows:]

STATEMENT OF MICHAEL P. WEINSTEIN

Mr. Chairman, members of the subcommittee: thank you for allowing me to speak before you today.

My name is Dr. Michael Weinstein. I am a board certified pediatrician practicing in Fort Valley, Georgia. I am the chief of pediatrics and of the newborn nursery at the Peach County Hospital in Fort Valley, and run the only pediatrics practice in the community.

In addition, I write a weekly medical column for the Macon (Georgia) Telegraph and News. Topics vary from medical "how-to" to medical politics. The article I wrote for the October 15, 1986 issue of the Macon Telegraph concerned physician-dispensing of drugs. I had had little familiarity with this subject prior to watching a segment of the CBS Television News "Nightwatch" program early on the morning of October 14, in which the topic was discussed. I have no vested interest in physicians either dispensing or not dispensing drugs, other than the interest I have as a physician and a member of the community in the continuing excellence of medical

care in this country. I believe that the practice of physician-dispensing endangers this excellence.

My community is a small city in a rural part of middle Georgia. The population is about 10,000. We have ten active physicians in town. Many residents are also treated by physicians in the nearby larger cities of Warner Robins and Macon. Five pharmacies serve the community. Two of them (the chains) are open 7 days a week; the others are open six. Most of the pharmacies will deliver to patients' homes. At least three of the private pharmacists will come out to fill prescriptions for their customers at night, on Sundays, and on holidays, when necessary.

Patients visiting the emergency room or seeing their physicians after hours are routinely given samples of whatever prescription they need until usual working hours when the pharmacies are open. In doctors' offices, these are, and have traditionally been, free starter samples, provided by the pharmaceutical companies without charge to the physician to give without charge to the patient.

In short, at least in my community, physician sales of drugs are not needed for ordinary patient care, neither during the ordinary working days, nor in the off-hours.

I believe that the widespread policy of physician dispensing, particularly if initiated by the "pre-packaging" companies, would skim off the most common drugs and would drive some or perhaps all of the pharmacies out of business. Should this happen, it would be impossible to fill all the other prescriptions that are not on the "top 30 hit list," so to speak, because there would be no pharmacies to do so. Perhaps in the short run patients would benefit from "one-stop shopping" and the POSSIBLY lower prices a physician might charge (a recent issue of the AMA News notes that many physicians are charging far MORE than the retail pharmacies), but in the long run drug availability would suffer, costs would increase, and the quality of medical care would be compromised.

The AMA is concerned about the loss of "checks and balances" in the system when the person prescribing the drug is the same as the person filling the prescription, and so am I.

I believe that I can best summarize my views on this matter by reiterating the six points I made in the original article:

1. Physicians would be pressured economically to dispense the drugs they stocked, although others might be better or cheaper, and to dispense a drug about to go "out of date" when others might similarly be more appropriate.

2. It may be convenient for the patient initially to avoid going to a pharmacy to fill the prescription, but it is not in the patient's interest to return to the office for every refill. First, physicians' offices are not open as long as pharmacies are. Secondly, there has been a suggestion from some that a physician might collect an office fee for every refill revisit, something that does not occur in any ordinary trip to the pharmacy. Under any circumstances, patients will find it far less convenient to get their refills at the doctor's office than at the drug store.

3. The after-hours argument is not convincing. As I described above, in small towns pharmacists will "open-up" for their patients. In large cities, there is usually a store open late or even all night. And samples at the office and the emergency room fill the remaining void.

4. Regardless of intentions, physicians cannot take time that would otherwise be profitable (seeing patients) to dispense drugs at a small markup. Either the system will not work, or the doctor will charge a higher and higher markup to pay for his time.

5. If all or even a significant number of doctors did this, and skimmed the most common and/or profitable drugs, pharmacies could not stay in business to provide the uncommon ones. Medical care would suffer.

6. The medical profession is very sensitive about others encroaching on its own territory, and with good reason. I do not believe that non-medical personnel should provide medical care. I do not believe that independent nurse midwives or nurse practitioners should be licensed to "practice medicine." I do not believe that optometrists should treat eye diseases. I believe that the diagnosis and treatment of diseases should be the responsibility solely of the physician. And I believe that we should similarly not encroach on others' territory. Dispensing, with the exception of injections and of free samples, is the responsibility of the pharmacist, and it should stay that way.

I have appended the text of the original article:

(From the Macon Telegraph & News, October 15, 1986:) Early yesterday morning I found myself watching one of those all night network news programs. A pediatrician from San Diego, California and a pharmacist were arguing about the trend in California for physicians to dispense medicines directly from their offices, bypassing

the pharmacy. Since this trend is current in California, where all trends start, it might work its way East, so we should pay it some attention.

The doctor's arguments were these:

1. His patients demanded it. Other medical groups were doing the same thing, so he was forced into it.

2. He stocks 34 drugs, including all the most commonly used medications in pediatrics, so he rarely has to write a prescription for the pharmacy to fill.

3. It is helpful when he sees patients after hours when pharmacies are closed.

5. He makes a profit, and it helps to pay his overhead.

6. He nevertheless charges less than the average pharmacy in his city, thus saving his patients money.

The pharmacist's arguments were these:

1. In most large cities, where this practice is emerging, at least some pharmacies are open until midnight, which takes care of the bulk of prescriptions, even after-hours emergencies.

2. Most doctors offices are not open late, and most doctors do not see patients after hours, and even those who do will dispense the bulk of the prescriptions for ordinary daytime visits.

3. Untrained personnel in the physicians' offices may be given the task of dispensing medication, a task only trained personnel do in a pharmacy.

I didn't watch the whole segment, but for most of the debate the doctor gave the more convincing arguments; the pharmacist was constantly on the defensive and her arguments were weak. It happens, however, that the doctor's arguments were totally wrong and the pharmacist's position was in my opinion, completely right. Here is what was so wrong about the doctor's arguments; the pharmacist was constantly on the defensive and her arguments were weak. It happens, however, that the doctor's arguments were totally wrong and the pharmacist's position was, in my opinion, completely right. Here is what was so wrong about the doctor's arguments:

1. Although he stocked 34 drugs, including the "six or seven" most commonly used in pediatrics, there will be times (admittedly not many) that he will need something else. He will either write a prescription, or be tempted to use a less-than-optimum drug that he has in stock. There may also be pressure to be better or equal but less expensive. There is a very great benefit to the patient when the one who chooses the drug (the physician) has no potential gain or loss from its sale. Such a benefit is only seen when the prescriber and the pharmacy are separate.

2. It may be convenient for the patient initially to avoid making another stop, but it is not convenient for patient or physician when the patient needs a refill. Then it becomes a hassle for both. Most patients do NOT consider going to the pharmacy an inconvenience.

3. The after-hours argument is totally specious. Most large cities have at least one pharmacy open late. In most small cities and small towns pharmacists will open up to dispense medication for regular customers. But neither is necessary. Almost all late night prescriptions, especially in pediatrics, are for antibiotics, usually for ear infections or strep throats. All doctors, particularly pediatricians, have a drug closet full of samples given them free by the drug companies. The standard antibiotics are ALWAYS included. I have never seen a pediatric office that was unable to give free samples "to go through the night" of any standard medication that was needed.

4. The doctor claimed that the small profit on dispensing drugs helped him meet his overhead costs. Baloney. In order to be able to stock that many medications without having most of them go out of date, the doctor's practice would have to be very large. In a large or busy practice, a labor-intensive procedure such as mixing and dispensing and labeling a medication is not cost-effective, because in the time necessary to do it he could have seen another patient. I don't buy his argument.

5. Finally, if all doctors did this, and skimmed the most common prescriptions from the pharmacies, leaving the pharmacies only the rare of complicated prescriptions, there would be no pharmacies left in business to do it. Physicians and their patients would suffer.

Doctors should leave the business of dispensing drugs to the pharmacies. As a profession, we are so concerned with others trampling on our toes, I find it hard to believe that a physician could go on national television and argue that we should trample the toes of others, especially when our patients' welfare would be compromised.

I thank you for your time.

Mr. WAXMAN. Thank you for your testimony. Let me just ask a few brief questions.

On this question of should the Federal Government be involved or not, it's always a dilemma for us.

Dr. Taylor, are you a member of the American Medical Association?

Mr. TAYLOR. Yes, sir. I've been a member of the AMA since 1959.

Mr. WAXMAN. Now, we have issues here at the Federal level under Medicare. Medicare is the leading purchaser of health care for the elderly and provides a large portion of the medical dollars that go into the whole health care system. We get questions all the time at the Federal level such as should we let optometrists be reimbursed, if they're licensed at the State level. Should we let podiatrists be reimbursed. Should we let nurse midwives be reimbursed, if they're licensed at the State level?

The AMA has consistently taken the position that State licensure shouldn't predominate under the Medicare law, because some of these people, notwithstanding the fact that they are acting within their licensure at the State level, shouldn't be infringing on what is the doctor's prerogatives.

Do you think we ought to change the Medicare law to say that the States ought to decide who should be reimbursed under Medicare?

Mr. TAYLOR. No. There are a number of changes that Medicare needs, but I don't think that's one of them.

Mr. WAXMAN. You don't think that's one of them, OK.

So what we have here is Federal Government, often under the influence of the AMA—and I'm not saying the influence is necessarily bad, because I agree with many of their positions on this—but they have urged us at the Federal level to establish certain practices which become the landmark position for these people in the practice of their professions all around the country.

Now, Dr. Hampton, you indicated that the doctor must be involved in knowing about generics, and you indicated that the Waxman-Hatch bill, which provides for more generics to be available, would be very helpful in lowering the cost for patients. One of the problems we've had is that even if there is a generic, the doctors know about the drugs that the brand-name companies have been selling. In fact, sometimes they sell those drugs and the idea of prescribing those drugs to their patients through junkets to the Bahamas, through high-priced educational and propaganda techniques, so a lot of these doctors don't know about the generics, and they just don't get opportunity to hear about the generics in the same way.

Do you think there's a danger that because now they'll have the opportunity to get your and your colleagues' repackaged drugs, that to make a profit out of it, the ones they're going to start prescribing will be the ones that they have available to them already in hand as the regular kind of prescription, which may end up being higher for the patient, because after all, there's going to be a markup for the people who are doing the repackaging?

Mr. HAMPTON. I think you're correct, but in general I think there are two issues.

One, they are not as familiar with generic manufacturers and tend not to trust them as much. I think that is a fact.

On the other hand, they are not aware of the tremendous cost differences, and once they see these costs, which in most cases they have never seen before, you'd be surprised at the switching to generics that goes on. In fact, I could quote some brand versus generic prices or costs and——

Mr. WAXMAN. Well, why should I assume that a repackager of pharmaceuticals is going to introduce the doctor to what will be a lower price for the patient?

It seems to me that if I were going to go into the business of repacking drugs to sell to doctors who in turn sell to their patients, I'd give the physician the drugs they already know about, which are the more expensive brand-name drugs. I would give them to the physicians in convenient packaging, so that they could just turn around and sell that higher-priced drug, which would have a markup for the doctor to get a profit, and have them prescribe those.

Mr. HAMPTON. But you're assuming because the price is higher on the drug in total that the markup is the same. And in fact, the markups on generics are much higher than they are on brands. And some of the very expensive brands, like Tagamet, have minuscule markups, in the neighborhood of a dollar, a dollar and a half.

Mr. WAXMAN. I'm assuming that you're correct when you say that the doctors don't know about the prices of drugs, and they respond to who is selling them the drugs, and so instead of the brand-name companies pushing drugs, it will be a new outfit that will be pushing drugs, and that the consumers are not going to get any benefit on price; in fact, they're going to have to pay a higher price.

Mr. HAMPTON. Well, we personally offer every drug in the U.S. pharmacopoeia, and they take their choice But one of the things that does happen is, when they see the difference in cost, they start switching to generics.

Mr. WAXMAN. Thank you very much.

Mr. Wyden, I'm going to call on you and also turn over the gavel to you, because I have another meeting at this time, and we will finish with the members' questions.

Mr. WYDEN [presiding]. Gentlemen, thank you all for your testimony. I know it's been a long day, and I have just a few questions, and then I'm going to turn to my colleagues.

I believe, Mr. Hampton, you heard me read the advertisement where you encourage doctors to write 50 prescriptions per day, which would equal $200 per day or $52,000 a year, just in terms of writing prescriptions. I don't see how anybody could do that responsibly in 1 day.

Mr. HAMPTON. Well——

Mr. WYDEN. Hear me out.

If I met with a constituent every 15 minutes for 10 hours a day, I'd only meet with 40 constituents. But you're encouraging people in your advertisements to make $52,000 a year by writing 50 prescriptions a day.

Now how can that be done in a responsible fashion?

Mr. HAMPTON. We're not encouraging physicians to write prescriptions. We're assuming that they will write what they will write.

Mr. WYDEN. Do you think that can be done in a responsible way?

Mr. HAMPTON. Yes. The second issue is that when we put the $4 markup in our original ad, that was roughly what we assumed the chain drugstore would be earning. We have since found that our average is more like $3, and we've revised our numbers accordingly.

But, in fact, our physicians are more competitive than chain drugstores, and they certainly are more competitive than independent retail stores.

Mr. WYDEN. But you don't have any proof other than the industry studies. Are there any independent analyses that show this?

Mr. HAMPTON. With every customer, we, first of all, give them national survey data of four different levels of prescribing. In addition to that, we do a prescription cost study in their exact area, and we help them peg their prices at or below generic levels.

Mr. WYDEN. Is there an independent study that's been done by a group other than yourselves to show that there are price savings? I just need a yes or no on that.

Mr. HAMPTON. I'm not certain of that.

Mr. WYDEN. Let me make sure it's understood, the way the markup works. With the role you're playing, it seems to me that there are going to be three markups on the way to the consumer's pocketbook.

The first markup is when it goes from the manufacturer to the repackager. The second markup will be when it goes from the repackager to the physician. The third markup will be when it goes from the physician to the consumer. Isn't that correct?

Mr. HAMPTON. Well, that's true, but even the total of those markups are less than the markups that go through the retail outlets.

Mr. WYDEN. You have contended that, but in answer to my previous question, you have no independent evidence of that fact at this time. I want the record to show this.

With respect to Dr. Taylor and, I believe, Dr. Fields, the points that you make about the concern of the family physician, I share in their entirety. I am very concerned, about the problem of the rural physician. We attempt to deal with that in the legislation. We're going to have a markup tomorrow, and I'm planning to be very sensitive to the concerns of my rural colleagues, because I think that is important.

In regard to emergency provisions my bill tries to provide significant leeway. In that regard it deals with the injectables, vaccines, and things of that nature. I just want it to be clear to you and to the family physicians the exceptions in my bill to limit physician sales has been to respond to your concerns and the kinds of concerns that my colleagues in rural areas are going to have. I just want to make that clear to you.

With respect to you, Dr. Fields, your point about enforcement at the State level is a very good one, and we believe that that can be done under my legislation. I think it's highly appropriate to do it under my legislation, and we may want to spell that out a little bit more. But I think enforcing it at the State level is a very sensible and appropriate idea, and your suggestion is helpful there.

I gather you would like to make an additional comment?

Mr. RICHARD FIELDS. If I may, Mr. Chairman. May I call you "Mr. Chairman" now?

Mr. WYDEN. Sure.

Mr. RICHARD FIELDS. I didn't have much notice to be prepared to come up here, but I did try to get a pretty good feel for what was going on in the Commonwealth of Virginia.

They advise me that the problems of enforcement would not be major—would not be major, in view of the fact that they are involved in enforcing other things; however, they do say that they would require many additional people for enforcement of this, and that, of course, would cost money.

Mr. WYDEN. Dr. Weinstein, is there anything further that you would like to add on that point?

Mr. WEINSTEIN. I'd just like to say that from the point of view of a pediatrician, I would hope that this legislation in no way prohibits particularly pediatricians and family practitioners from administering immunizations, vaccines, and injectable antibiotics that a pharmacy clearly cannot administer.

Mr. WYDEN. Yes. The point is addressed specifically in the bill, and your concern is taken care of.

I want to recognize my colleague from Illinois.

Mr. BRUCE. I just wonder, Dr. Weinstein, just following up, given the avariciousness of the doctor and his inability to control this, why wouldn't you want a nurse assigned at the pharmacy to give injectables? I mean, why wouldn't that be more reasonable? Why should you give those, rather than dispensing drugs? Why is there any distinction in your own mind?

Mr. WEINSTEIN. Well, from my own point of view, if there were a nurse at the pharmacy who would give the injectable and bear the responsibility of malpractice if some awful thing were to happen, I think that would be preferable.

Mr. BRUCE. But then the same ethical problem, won't the doctor overprescribe shots and do things that he shouldn't be, just as he's doing with the dispensing of medicine.

Mr. WEINSTEIN. No. I think vaccines are—the schedule for immunizations is—has been stated by the Public Health Service, by the Pediatrics Academy, and by virtually every State, and we just follow a protocol.

The number of injectable antibiotics that are given in a medical office are so minuscule that they really aren't any different than any other form of therapy.

Mr. BRUCE. Thank you.

Mr. Hampton, the chairman was concerned about costs and whether or not you could be competitive in bringing down costs or whether your costs would be higher or lower.

You have no specific data that shows that you can provide 50 tablets of any particular item at cheaper cost?

Mr. HAMPTON. Yes. We have considerable data. In fact, we surveyed we do this constantly, so we do have data. But we did survey three of the most competitive chains in the Chicago area, and I have all the data here that I could submit. But I would like to point out a couple of products.

Cytoxan, for example, a very common cancer drug, the product cost is $42.68, and the range of markup over that cost by the three

most competitive chains in the Chicago area was between $18 and $16. If that would have been one of our products, it would have been marked up $3. And there are numerous other examples.

Procan SR, the brand is $14, the generic is $3.15, and yet the generic sells for $12, a $9 markup, in the three most competitive chains in the Chicago area.

We have numerous examples like this. This is the reason that physicians can compete, because there is excess profit in the retail system.

Mr. BRUCE. I just wondered. Mr. Hampton, if you were overpriced in every other pharmacy, I take it they would take out ads saying that your drugs are higher than theirs.

Mr. HAMPTON. I'm sure they would.

Mr. BRUCE. I would think that would be a wise position to take. I'm just curious. You mentioned that every pharmaceutical is available to the physician; is that correct?

We've had testimony that the average physician only has about 50 different medications in his office. Do you know what your average would be in a physicians office?

Mr. HAMPTON. It's between 25 and 50. We have physicians as low as 6, and we have them as high as 100-and-some.

Mr. BRUCE. And why doctors have a—physicians have a differing amount?

Mr. HAMPTON. For each physician, their principal treatment regimens involve only—or most of the treatment regimens involve only about 50 drugs. It's not a limitation; it's what they do.

Mr. BRUCE. Dr. Taylor, you mention in your testimony skills taught by accredited family practice residency programs and the AAFP continuing education programs. Can you tell me what skills you learn in these programs and how they prepare a physician to dispense drugs?

Mr. TAYLOR. The basic information and training takes place in medical school, of course, and then in the residency programs, a great deal more is learned there on site when you are dealing with patients and carrying the primary responsibility for their care during residency programs. In the continuing education programs, drug interactions, that topic is frequently seen on the agendas of meetings that take place in every State and virtually every town of any size in this country, and one of the reasons is that actual membership in the American Academy of Family Physicians requires 50 hours of approved continuing medical education every 3 years. That type of subject is frequently on the agenda.

I am not sure I understand, beyond that, what you mean. There are technical discussions as to what the drugs do, what their effects are, what their side effects are, the dosages, frequency of dosages and their interactions with other medications.

Mr. BRUCE. Including continuing education programs?

Mr. TAYLOR. Yes, sir.

Mr. BRUCE. Mr. Hampton, a couple of questions. One of the things of concern that was brought out by the two physicians here is if, in fact, physicians do prescribe the most common medications, what is it your belief will happen to the less popular, less well-known pharmaceuticals?

Mr. HAMPTON. I think the less popular pharmaceuticals are being used, but what we are really talking about is what an individual physician does, not what physicians do at large. We have been adding products to our line at the rate of about 30 a week over the last month or so, and we basically put anything in the line that somebody asks for. I don't see any limitation, and I am sure that we carry many, many more products than the typical drug store.

Mr. BRUCE. Second, it did strike me as useful that chain drug stores, in particular—if you are being treated by two physicians or three or more or whatever, when they come in, oftentimes patients don't tell a physician he is under other medication. What is the protection for a patient when he goes to two different physicians and then gets prescriptions, the other doctor not knowing they are contraindicated to be given at the same time? You would have that protection with the chain drug when you walk into another outlet and get another prescription.

Mr. HAMPTON. You would if they went back to the same chain and they had that system. Our records are kept with the physician who did dispense the product.

Mr. BRUCE. So that is an advantage, then, to the chain drug store.

Mr. HAMPTON. Yes.

Mr. BRUCE. Thank you, Mr. Chairman.

Mr. WYDEN. Mr. Hampton, what assures that the physician charges what the repackager suggests?

Mr. HAMPTON. I am not sure I can answer the question, but I can tell you that in general, they want pricing help. We go to great lengths to help them get their formulary priced, and it is our belief that they follow the recommendations.

Mr. WYDEN. It sure didn't happen in my home State with that 200 percent markup on penicillin. I know it wasn't anybody's suggestion to charge those kind of prices.

Mr. HAMPTON. Mr. Chairman, could I have one question?

Mr. WYDEN. Sure.

Mr. HAMPTON. Since this issue came up only 2 weeks ago and there is a hearing and a markup scheduled for tomorrow and there is really no evidence of overcharging that would put limitations on this in a very near-term basis, why don't you give us the time to commission an independent study of these facts? I think they may be very revealing to the subcommittee.

Mr. WYDEN. We will ask the questions.

We appreciate your suggestion, but certainly some of us who are in support of this feel that there is a great deal of evidence already to indicate a very serious conflict of interest. I want to ask you some other questions dealing with the services that you prescribe.

When a pharmacist fills a prescription, Mr. Hampton, if the patient needs 40 tablets, they get 40. If they need 50, they get 50. I realize many patients need the same quantity of certain drugs, but certainly not all patients need the typical quantity.

As I understand it, your firm puts a specific number of tablets into a sealed bottle. I have one of your prescriptions here, and it is 50 tablets. Won't this result in over or under-dispensing for the non-average patient who might need 40 or 80?

Mr. HAMPTON. Basically, the number of tablets or capsules in the container that we give the physician are the number that he requests from us. I think I would have to have a pharmacist or a physician answer that question beyond that. Basically, we don't limi them. We give them what they want.

Mr. WYDEN. That makes our point. You would need a pharmacist to answer the question of whether or not the exact amount is given.

Mr. HAMPTON. Well, we have pharmacists. I just don't happen to be one personally.

Mr. WYDEN. Tell me a little bit about your p' macists. What is their training? How many do you have? Tell us ut their role in your business.

Mr. HAMPTON. We have two and we have just added another one. The original one was one of the founders of the company. He is a very experienced individual. He has worked for three major pharmaceutical firms. He has also run his own drug store and has worked in several other drug stores in the area. More recently we have hired a young pharmacist who is on a Walgreen training program, and he has been rotated around to a number of different Walgreen stores. We have also hired consultants in the packaging area that have given our people extensive training.

Mr. WYDEN. The only other point that I wanted to make was one for the record which has come up on a number of occasions. It deals with medical practice and drug commerce. Dr. Taylor, perhaps you could help us get into this.

Like the AMA, you oppose H.R. 2093 and similar legislation. You view it as Federal intervention into the practice of medicine. It seems to me the simple act of selling drugs is hardly a central part of the practice of medicine. Prescribing drugs, of course, is the practice of medicine, just like diagnosing illness and performing surgery. Since dispensing is done every day by pharmacists, it would seem to be central to the practice of pharmacy, if to any profession.

I would like, and I think this would be helpful to the subcommittee, for you to tell us why you consider the act of selling drugs part of the practice of medicine.

Mr. TAYLOR. Well, sir, I would go back to the original situation that would say that if the physician is licensed to decide which medication to give, he is also entitled to decide the mode in which it is administered, whether that be by injection or by a capsule, by a tablet, by liquid by mouth or other orifice, or by application on the skin. I fail to see that there is a great difference as to whether one is permissible and the other isn't, the mode of administration. To me it is immaterial. I think it is all part of the same process.

I would like to make another observation, Mr. Chairman. I am being pushed by some of my people for time. I think it is extremely interesting to sit here and listen to all the pharmaceutical people today who are very concerned about physician prescribing. In my area of South Carolina, there is no threat to them from physician prescribing, but they are absolutely in a panic about what is going on with the managed care industry, taking bids from one chain or another and excluding whole blocks of individual pharmacists. I

think it is a little unique to listen to all of this testimony and not hear any concern.

The other thing would be that if your committee does consider further this particular item, we would be interested in seeing how you approach the idea of providing balance. We talked a little earlier about balance between prescribing and dispensing, and then the reverse of that with the pharmacist dispensing and prescribing. It would be interesting to see that.

Mr. WYDEN. I want it to be clear that I am interested as a sponsor of this legislation in being consistent. I think doctors should be doctors, and pharmacists should be pharmacists. That is the point of the exercise.

I think the only other point that I want to make, because we have discussed this at some length today, is that there really is a dramatic difference between doctors dispensing drugs and ordering xrays, clinical tests and diagnostic procedures. Patients go to doctors because they are trained to evaluate their need for diagnostic tests. Physicians are not trained at this point to manage pharmaceutical products or dispense drugs. They are not trained to evaluate potential conflicts with other drugs the patient may be taking, to mark packages with warnings or to instruct the patient when to take a drug or how often.

Moreover, the physician is subject to review by peers, insurance companies and PRO's when they order those diagnostic tests. There doesn't seem to be the same kinds of rules for safe and effective drug pricing, drug distribution or management.

I want to recognize my colleague from Illinois.

Mr. BRUCE. I guess I have learned something, too, and that is I am still convinced that physicians, when a patient walks in, has concern for the patient as a whole and they treat the patient as a whole. If a blood test is required, they will make an ethical decision on whether or not there ought to be a blood test and whether there will be an xray. When they get down to the young woman or young man walking out of their office and needing additional medication, he will make an ethical decision on whether or not to prescribe medication.

If he prescribes it, I think he will do so ethically, and if he decides to fill it himself as opposed to having it filled at a pharmacy, at that point there seems to be a difference of opinion here, that somehow at that point the doctor says ethics go out the window, malpractice insurance premiums, I don't care, I am going to do whatever I want to do with who gets to sell the drugs.

I don't think that occurs. I just don't think it occurs. I think the doctor is as ethical in making that ultimate decision as to who is going to fill the prescription as he has been in all the other decisions he has made with that patient all the way through the visits and the time, and he is going to see him again, he hopes, and all the other things that occur between a doctor and a patient relationship.

It seems to me that this aberration occurring in drugs just doesn't appear to me. I have had a chance to work with physicians for a long time in rural southern Illinois and hospital administrators. I just don't see this big ethical problem for doctors. They give away and dispense free medication all the time, and we don't seem

to see that they have some big ethical problem there, but all of a sudden, when they are going to put it in a package and hand it to somebody, that they will do unethically. I don't agree with it.

I think that the situation as we find it for southern rural Illinois is one that we ought to continue, and that is to allow physicians, within the constraints of all the problems they have of physicians' examining boards, State agencies of review, to dispense medication. The testimony here was less than 5 percent of the physicians across the United States are even doing this. If that is the case, 95 percent of them are not doing it, and you would have to say among the 5 percent that are doing it, how many of those are creating a problem? In my State, not a single one, so I think that I have learned a great deal and I think physicians can continue to do as they have done in the past, and that is to dispense medication properly.

Mr. WYDEN. I think my colleague has made a number of important statements. My perception is that under my legislation, life in southern rural Illinois isn't going to change very much. I would hope that because of this, we could prevent some problems that might occur down the road in areas where there is a very competitive marketplace. Unfortunately, there is a financial temptation that might involve that small minority in the profession who would fall prey to it.

Nobody is saying that the vast majority of physicians in this country are avaricious or interested in ripping people off. The question is, particularly in the very competitive environment in a lot of areas, should we create a situation where structurally there is a temptation to put profit before patient care? I want to work very closely with my colleagues between now and tomorrow morning when we have a markup because my colleagues and all my friends from the rural areas have made a number of very important points. I want to make sure that when we mark up tomorrow, my bill does not affect life in rural areas in any dramatic way. I don't think it will, and I want to work with my friend between now and tomorrow to make sure it doesn't.

Mr. BRUCE. Thank you, Mr. Chairman.

Mr. WYDEN. Witnesses? Any further comment?

[No response.]

We are adjourned.

[Whereupon, at 5:10 p.m. the hearing was concluded.]

[The following statements were submitted for the record.]

Statement by Francis W. Parnell, M.D., Chairman of the Board,
Parnell Pharmaceuticals, Inc., San Rafael, California

Subject: Physician Dispensing

"Parnell Pharmaceuticals actively supports and participates in a physician dispensing program.

With such a program, patients can be given medication immediately and at less cost. Physicians have greater control over the course of therapy and the patient's compliance with the prescribed dosage is much improved.

The bond between physician and patient is enhanced which is many times the most important ingredient in patient improvement.

Physician dispensing of drugs is as old as the profession itself. At a minimum, all physicians dispense samples, some even injectables. In some specialties, dispensing of such items as contact lenses, diaphragms and other devices is routine. In my field, dispensing of hearing aids is becoming more common.

We oppose the passage of any legislation limiting the practice of physician dispensing. Physicians have always dispensed drugs and should be able to continue doing so.

We agree with the position the Federal Trade Commission has taken saying it increases service and price competition among practitioners, and between practitioners and pharmacists to the benefit of consumers."

Dr. Parnell has been practicing otolaryngology for nearly twenty years. In addition to his duties at Parnell, he has his own private practice in Greenbrae, California.

He is a Fellow, American Academy of Otolaryngology-Head and Neck Surgery and is a Fellow, American College of Surgeons. He is President-Elect of the Northern California Chapter of the American College of Surgeons.

STATEMENT

OF

JOHN A. RUPKE, M.D.

PRESIDENT

NATIONAL ASSOCIATION FOR AMBULATORY CARE

The National Association for Ambulatory Care is the national organization of ambulatory care centers. We are a young industry and a young association. There are some 4,000 centers furnishing walk-in medical services in approximately 50 million patient encounters every year. Most ambulatory care centers are owned and operated by physicians.

The great majority of these ambulatory care centers are open 12 to 16 hours per day, 365 days a year. We fill an important niche in the health care marketplace. First, we provide an alternative to the hospital emergency room for patients with urgent problems, and those for whom a hospital emergency room visit is too expensive. Second, we prevent an unnecessary distraction of the hospital emergency room staff from more seriously ill patients. Third, we provide extended hours access for patients whose family physician is not readily available in the evening or on weekends. Fourth, we provide an entryway into the medical delivery system for patients who have not yet established a relationship with any other provider of care.

According to a 1986 survey we conducted, approximately forty percent (40%) of ambulatory care centers now maintain a program for dispensing basic medications for their patients' convenience and welfare. We generally utilize prepackaged dosages of the most commonly prescribed medications. Analgesics and antibiotics are the medications most frequently dispensed. Most are generic. A copy of the survey is attached.

Our patients greatly appreciate the option of acquiring needed medications conveniently without need for a separate trip to a pharmacy. We often provide drugs during hours when area pharmacies are already closed for the evening. We have found that approximately forty percent (40%) of our patients choose to purchase the needed medication from our centers. Many employers have encouraged us to make medicines available on site. Their employees being seen at our centers during the workday can then reduce their time away from the job.

We strongly oppose the proposed legislation that would effectively prohibit our centers from dispensing prescription medications. It is unnecessary, anticompetitive and anticonsumer.

Physician dispensing has generated considerable tension between certain pharmacists and medical practitioners. Efforts have been made to curtail, and even prohibit, physicians from dispensing medications in numerous states. In every case such efforts have been rebuffed by the state legislatures on behalf of their citizens. Now federal legislation is proposed. Such legislation should not be adopted for the following reasons:

First, it is unnecessary. No evidence or studies show that overprescribing, overcharging or quality control is a problem where physicians dispense a limited formulary of prepackaged

medications. Arguments have been made that any hidden physi ian ownership interest in community pharmacies should be disclosed to unsuspecting patients. However, there is no deception or hidden agenda where an ambulatory care center simply offers patients the choice of obtaining needed medications on site.

The assumption that patients are unknowingly pressured or swayed to purchase overpriced drugs from their doctor is premised on a view of the patient as a passive recipient of health care and not an active participant in his or her own health care. A view of today's patient as passive is contrary to all of our recent state and national initiatives to improve quality and control costs. Patients benefit from competitive market forces, more efficient forms of health care delivery, and their exercise of active consumer choice.

Some pharmacists assert that physicians should have the checks and balances of a second party examining the proposed prescription. Physicians already have their own peer review organizations which give intense scrutiny to physicians' practice of medicine. The accrediting bodies of the ambulatory care centers, namely the Joint Commission on Accreditation of Hospitals and the Accreditation Association for Ambulatory Health Care, have commenced programs to scrutinize closely the method and practice

of dispensing medications. We must all live by square corners and the ambulatory care centers place great emphasis on the appropriate labeling, packaging, and dispensation of medication. The National Association for Ambulatory Care has also undertaken steps on behalf of better patient service to prevent polypharmacy and the indiscriminate refilling of patient prescriptions.

Second, the proposed legislation would be anticompetitive and anticonsumer. We refer you to the comments provided by unanimous vote of the Federal Trade Commission opposing this sweeping legislation. As the FTC has noted, physician dispensing is in the public interest. It benefits consumers by maximizing the number of qualified sources from which they may purchase prescription drugs. It enhances the incentives for pharmacists to offer lower prices and additional services. It also provides access when many drug stores and pharmacies are closed. It saves patients time away from work and their other activities.

Third, the proposed legislation would impose an unwarranted and rigid federal standard in an area that has been and properly is the subject of individual regulation by the states. A turn to a federal solution to any perceived problem should only come if the states are unable to address a truly national problem. Here it is the opposite. The states have the

licensing programs in place to challenge any true misconduct. No evidence exists of a real proolem that warrants violation of basic principles of federalism.

Finally, the "conflict of interest" shibboleth is raised -- that physicians will engage in improper prescribing practices because of their potential financial gain from the sale of medications. The physician in today's society must make many decisions regarding his or her patients' care that would affect the doctor's pocketbook. This prospect exists whenever a doctor recommends that a patient come back for another visit, have surgery, or have an x-ray or laboratory test performed in the doctor's office.

To act in patients' best interest as a fiduciary in such situations is the doctor's professional responsibility. There is no basis for singling out the dispensing of drugs as a special conflict of interest.

We note, for example, that pharmacists properly pride themselves on their ability to make recommendations to customers regarding a sound choice of over-the-counter non-prescription medications. No one is proposing, however, that pharmacists be barred from selling over-the-counter drugs.

In short, we believe the proposed legislation would serve only to free pharmacists from any outside competitive element, however small, at the expense of patient health care, convenience, and the public interest. To put all this in the best light, there is a conflict of duties as seen by the physician and the pharmacist. We seem to be oddly met in a confrontation of compassion. This is not as it should be and we deplore the occasion.

We believe the issue of physician dispensing is being commercialized and exploited at patients' expense. We believe this threatens the professional fraternity which has always existed between physicians and pharmacists. To this end we have sought to negotiate the issue as the pharmacists perceive it at the state and local level. We have chosen not to unduly alarm our patient population or the companies whose sick and injured employees we care for, with reports that a valuable service to them is being threatened.

We would be pleased to cooperate in a study to examine pricing and prescribing patterns where ambulatory care center physicians dispense medications. The current proposal, however, shows no recognition of patients' rights, welfare, preference or convenience. We vigorously oppose the curtailing of physicians' medical services, and the apparent preferential treatment of pharmacists' commercial interests.

NATIONAL ASSOCIATION FOR AMBULATORY CARE

PHARMACEUTICAL DISPENSING STUDY

APRIL 1986

This study, conducted by the National Association For Ambulatory Care (NAFAC), considers the pharmaceutical dispensing activities of ACCs in the U.S. As such, this report represents the most current and comprehensive information on dispensing activities of ACCs. Overall, 540 ACCs nationwide are represented in this survey. If the total universe of ACCs is estimated at 2700 centers, this survey contains a 20% sample and is, by statistical standards, representative of the industry as a whole.

The NAFAC Pharmaceutical Dispensing Study is intended to provide some general characteristics of both dispensing and non-dispensing ACCs. A total of 184 different ACC companies were surveyed, 87 (47.3%) of which dispense pharmaceuticals (Figure 4). The 184 ACC companies represent a total of 540 ACCs. Of these 540 ACCs overall, 225 (41.6%) responded that they were dispensing some pharmaceuticals. Thirty-five of the presently non-dispensing ACC companies reported that they plan to begin dispensing within the next two years (Figure 17). Therefore, it is estimated that by 1988, 56.8% of all ACC companies will be dispensing (this projection is fairly conservative). The projection for total number of centers dispensing is similar--about 65% of all ACCs should be doing some type of dispensing by 1986.

The survey results are presented in the form of figures. It is envisioned that the best way to use the results presented here is to refer with the Table of Contents to find the most pertinent information. By choice, the figures are in their entirety, rather than as summary tables. In this way, each reader can utilize selected information for his or her own purposes.

GENERAL CHARACTERISTICS

The mean age of dispensing ACCs was 4.3 years (Figure 8), while the mean number of years the centers have been dispensing was only 2.023 years (Figure 6). Clearly, the dispensing of pharmaceuticals is a new trend in the industry. There is no significant difference between the age of center and its dispensing activity. In other words, when comparing those centers which are dispensing with non-dispensing ACCs, there is statistically no difference in the mean ages (using a Student's t-test on the means). However, as one would expect, the linear correlation between age of center and number of years dispensing is fairly high ($r=.72$, $p<.001$) (Figure 11). This simply means that the longer a center has been open, it is more likely to be dispensing pharmaceuticals.

Dispensing activity was further characterized by the number of outside and in-house prescriptions filled per day. The mean number of prescriptions filled in-house was 22.1 per day (Figure 14), while the mean number filled

outside was listed at 27.7 prescriptions per day (Figure 13). We can define a ratio of in-house to outside prescriptions filled per day as 1.6 to 1, based on a sample of 78 companies (Figure 15).

Using an average of $4 per prescription, a center should average $ .40 per day or $3,972 per month in dispensing revenue. Further, dispensing can enhance an ACC's competitive posture in the market, as the average charge for a prescription is $13, according to the American Pharmaceutical Association. Thus, ACCs, on the average, can offer the consumer a potential savings of 60% on their prescription medications.

Of 77 ACC companies, the mean number of different drug items dispensed was 52.2, with a median of 30 items (Figure 19). Overall, it appears that dispensing activities accounted for a mean of 6.44% of total revenues per ACC (median=5.0%) during 1986 (Figure 16). The average dollar inventory of prepackaged pharmaceuticals was $3,897 per center (median=$1,500) (Figure 31). Dispensing ACC companies reported that their dispensing activities were increasing at an average of 7.61% per month (median=5.0%) (Figures 35 and 36). Clearly, pharmaceutical dispensing is becoming an increasingly important factor in terms of overall revenues for the average ACC. The strength of this statement is illustrated by the strong linear correlation between the number of in-house prescriptions filled and the dollar inventory of prepackaged pharmaceuticals (r=.8793, p=.001) (Figure 37). Figure 38 shows the dollar average inventory of pharmaceuticals by the in-house number of prescriptions filled per day. Figure 39 illustrates the number of years dispensing by the dollar average inventory of pharmaceuticals and in-house prescriptions filled per day. An interesting note to the relationship between the number of years dispensing and the dollar average inventory of pharmaceuticals is found in Figure 32. There is little correlation between the number of years dispensing and the average pharmaceutical inventory (Figure 32). It appears that ACCs are dispensing generic pharmaceuticals over brand names at about a 1 to 1 rate (Figures 33 and 34).

A further characteristic of dispensing practices is who is doing the dispensing. Only 8.5% of the dispensing ACC companies employed a part-time pharmacist (Figure 41), while the corresponding figure for full-time pharmacists was 6.5% (Figure 42). By far, the majority of dispensing is done by both full-time physicians and nurses (76%) (Figure 43).

An interesting feature of the survey was that out of the 87 ACC dispensing companies, only 28 (35%) reported that dispensing led to an increase in overall patient census (Figure 44). However, 82 (94.3%) responded that dispensing increased patient satisfaction (Figure 45). Along these lines, "convenience to patients" was ranked as the top reason for beginning dispensing by 72.6% of the centers (Figure 48). The second major reason for dispensing was listed as a "source of additional revenue" (Figure 49). The most often listed third reason for dispensing was as a "service to attract patients" by 47.5% of the companies (Figure 47). Approximately 65% ranked the fact that "competitors were doing it" as the fourth most important reason for dispensing (Figure 48).

Finally, t-tests (not shown in Figures) were employed in order to differentiate the factors involved in determining whether or not ACCs plan to increase the number of drug items dispensed. There was no significant difference between those ACC companies planning to increase dispensing and those which did not on the basis of the following variables: the number of different drug items dispensed, the percent dispensing contributes to the total revenue of the ACC, the number of in-house prescriptions filled per day, the number of outside prescriptions filled per day, the age of the center and the number of years dispensing has been performed by the ACC company.

Similarly, plans to increase dispensing are not significantly effected by the percent by which dispensing is increasing per month. Little can be said about why an ACC company is actually planning to increase their dispensing. This may be the result of the fact that only 22 ACC companies plan to increase their dispensing (Figure 20).

PHARMACEUTICALS AND MANUFACTURERS

Respondents were asked to list their seven most common drug items dispensed. For clarity, this report has printed only the three most common drug items (Figures 21, 22 and 23). When the three tables are collapsed, it can be seen that the most commonly prescribed drug among ACCs is amoxicillin (26.3%), with penicillin vk (16.7%), erythromycin (15.5%), PCE-400 (7.8%), amoxil (7.1%), Tylenol (7.1%) and ampicillin (5.9%) following.

Similarly, respondents were asked to list their seven most common manufacturers of these drugs (Figures 30, 31 and 32). The results (from 157 responses) were as follows: Parke-Davis (24.8%), Biocraft Labs (22.3%), Danbury (14.6%), Abbot (8.9%), McNeil (8%) and Beecham (7.0%). In other words, it appears that two companies dominate the drug items dispensed by ACCs. Combining Parke-Davis and Biocraft Labs, 47.1% of the market is in the hands of these two companies

FIGURE 1.

STATE DISPENSING AND ITS LOCATION

Value Label	Frequency	Valid Percent
AK	1	1.1
AL	1	1.1
AR	3	3.4
CA	17	19.5
CO	3	3.4
CT	3	3.4
FL	7	8.0
GA	6	6.9
IA	1	1.1
IL	4	4.6
IN	2	2.3
KY	1	1.1
LA	1	1.1
MA	1	1.1
MD	2	2.3
MI	3	3.4
MN	1	1.1
MO	1	1.1
MS	2	2.3
NC	1	1.1
NJ	2	2.3
NM	1	1.1
NY	3	3.4
OH	2	2.3
OK	2	2.3
OR	2	2.3
PA	3	3.4
SC	3	3.4
TX	2	2.3
VA	1	1.1
WA	1	1.1
WI	2	2.3
WV	2	2.3
TOTAL	87	100.0

Valid Cases 87 Missing Cases 0

FIGURE 2.

STATE NON-DISPENSING ADV. IS LOCATED

Value label	Frequency	Valid Percent	Cum Percent
AL	3	3.1	7.1
AR	1	1.0	4.2
AZ	1	1.0	5.2
CA	4	4.2	9.4
CO	3	3.1	12.5
CT	1	1.0	13.5
FL	6	6.3	19.8
GA	3	3.1	22.9
IA	1	1.0	24.0
ID	1	1.0	25.0
IL	1	1.0	26.0
KS	1	1.0	27.1
KY	3	3.1	30.2
LA	2	2.1	32.3
MA	5	5.2	37.5
MD	2	2.1	39.6
ME	2	2.1	41.7
MI	7	7.3	49.0
MO	6	6.3	55.2
MS	1	1.0	56.3
NC	1	1.0	57.3
NE	1	1.0	58.3
NJ	8	8.3	66.7
NY	2	2.1	68.8
OH	2	2.1	70.8
OK	3	3.1	74.0
SC	1	1.0	75.0
TN	1	1.0	76.0
TX	14	14.6	90.6
UT	1	1.0	91.7
VA	3	3.1	94.8
VT	2	2.1	96.9
WA	3	3.1	100.0
TOTAL	96	100.0	

Valid Cases 96 Missing Cases 0

FIGURE 3.

Crosstabulation: 04A STATE ACC IS LOCATED
By 05 ARE PREPACKAGED PHARM DISPENSED?

05→	Count / Row Pct / Tot Pct	YES 1	NO 2	Row Total
04A				
AK	1	1 100.0 .5		1 .5
AL	2	1 25.0 .5	3 75.0 1.6	4 2.2
AR	3		1 100.0 .5	1 .5
AZ	4	3 75.0 1.6	1 25.0 .5	4 2.2
CA	5	17 81.0 9.3	4 19.0 2.2	21 11.5
CO	6	3 50.0 1.6	3 50.0 1.6	6 3.3
CT	7	3 75.0 1.6	1 25.0 .5	4 2.2
FL	10	7 53.8 3.8	6 46.2 3.3	13 7.1
GA	11	6 66.7 3.3	3 33.3 1.6	9 4.9
IA	13	1 50.0 .5	1 50.0 .5	2 1.1
ID	14		1 100.0 .5	1 .5

FIGURE 3 STATE BY DISPENSING STATUS

	Count / Row Pct / Col Pct	YES	NO	
IL	15	4 80.0 2.2	1 20.0 .5	5 2.7
IN	16	2 100.0 1.1		2 1.1
KS	17		1 100.0 .5	1 .5
KY	18	1 25.0 .5	3 75.0 1.6	4 2.2
LA	19	1 33.3 .5	2 66.7 1.1	3 1.6
MA	20	1 16.7 .5	5 83.3 2.7	6 3.3
MD	21	2 50.0 1.1	2 50.0 1.1	4 2.2
ME	22		2 100.0 1.1	2 1.1
MI	23	3 30.0 1.6	7 70.0 3.8	10 5.5
MN	24	1 100.0 .5		1 .5
MO	25	1 14.3 .5	6 85.7 3.3	7 3.8
MS	26	2 66.7 1.1	1 33.3 .5	3 1.6
NC	28	1 50.0 .5	1 50.0 .5	2 1.1

FIGURE 3: STATE BY DISPENSING STATUS (Continued)

		YES	NO	
	Count Row Pct Col Pct			
NE			1 100.0 .5	1 .5
NJ	31	2 20.0 1.1	8 80.0 4.4	10 5.5
NM	32	1 100.0 .5		1 .5
NY	34	3 60.0 1.6	2 40.0 1.1	5 2.7
OH	35	2 50.0 1.1	2 50.0 1.1	4 2.2
OK	36	2 40.0 1.1	3 60.0 1.6	5 2.7
OR	37	2 100.0 1.1		2 1.1
PA	38	3 100.0 1.6		3 1.6
SC	40	3 75.0 1.6	1 25.0 .5	4 2.2
TN	42		1 100.0 .5	1 .5
TX	43	2 12.5 1.1	14 87.5 7.7	16 8.7
UT	44		1 100.0 .5	1 .5
VA	45	1 25.0 .5	3 75.0 1.6	4 2.2

FIGURE 3: STATE BY DISPENSING STATUS (Continued)

Count / Row Pct / Col Pct		YES	NO	
VT	46		2 100.0 1.1	2 1.1
WA	47	1 25.0 .5	3 75.0 1.6	4 2.2
WI	48	2 100.0 1.1		2 1.1
WV	49	2 100.0 1.1		2 1.1
Column Total		87 47.5	96 52.5	183 100.0

FIGURE 4.

NUMBER OF ACC COMPANIES DISPENSING
(Note: Value is equal to the number of ACCs owned by a company); (Frequency is the number of respondents that own a certain number of centers). Of the 87 dispensing ACC companies which own a total of 540 centers, dispensing is performed in 225 centers.

Value Label	Value	Frequency	Valid Percent	Cum Percent
	1	51	58.6	58.6
	2	12	13.8	72.4
	3	9	10.3	82.8
	4	5	5.7	88.5
	5	3	3.4	92.0
	6	1	1.1	93.1
	7	1	1.1	94.3
	8	3	3.4	97.7
	21	1	1.1	98.9
	140	1	1.1	100.0
	TOTAL	87	100.0	

Valid Cases 87 Missing Cases 0

FIGURE 5.

YEAR DISPENSING BEGAN

Value Label	Value	Frequency	Percent	Percent
	1977	1	1.2	1.2
	1978	3	3.5	4.7
	1979	1	1.2	5.8
	1981	1	1.2	7.0
	1982	3	3.5	10.5
	1983	6	7.0	17.4
	1984	14	16.3	33.7
	1985	46	53.5	87.2
	1986	11	12.8	100.0
	.	1	MISSING	
		87	100.0	

FIGURE 6.

NUMBER OF YEARS DISPENSING

Years	Frequency	Valid Percent	Cum Percent
0.0	11	12.8	12.8
1.00	46	53.5	66.3
2.00	14	16.3	82.6
3.00	6	7.0	89.5
4.00	3	3.5	93.0
5.00	1	1.2	94.2
6.00	1	1.2	95.3
8.00	3	3.5	98.8
35.00	1	1.2	100.0
.	1	MISSING	
TOTAL	87	100.0	

Mean	2.023	Median	1.000	Std Dev	3.956
Minimum	0.0	Maximum	35.000		
Valid Cases	86	Missing Cases	1		

FIGURE 7.

YEAR FIRST DISPENSING ACC OFFENCE

Value Label	Value	Frequency	Percent	Valid Percent	Cum
	1951	1	1.2	1.2	
	1955	1	1.2	2.4	
	1972	1	1.2	3.6	
	1974	1	1.2	4.8	
	1978	2	2.4	7.2	
	1979	3	3.6	10.8	
	1980	7	8.4	19.3	
	1981	5	6.0	25.3	
	1982	12	14.5	39.8	
	1983	22	26.5	66.3	
	1984	17	20.5	86.7	
	1985	11	13.3	100.0	
	.	4	MISSING		
	TOTAL	87	100.0		

Valid Cases 83 Missing Cases 4

FIGURE 8.

AGE IN YEARS (DISPENSING ACCS)

Value Label	Value	Frequency	Valid Percent	Cum Percent
	1.00	11	13.3	13.3
	2.00	17	20.5	33.7
	3.00	22	26.5	60.2
	4.00	12	14.5	74.7
	5.00	5	6.0	80.7
	6.00	7	8.4	89.2
	7.00	3	3.6	92.8
	8.00	2	2.4	95.2
	12.00	1	1.2	96.4
	14.00	1	1.2	97.6
	31.00	1	1.2	98.8
	35.00	1	1.2	100.0
	.	4	MISSING	
	TOTAL	87	100.0	

Mean	6.277	Median	5.000	Std Dev	5.605
Minimum	1.000	Maximum	35.000		

Valid Cases 83 Missing Cases 4

FIGURE 9.

DIFFERENCE (YEAR OPENED - YEAR BEGAN DISPENSING)

Mean	2.110	Median	1.000	Std Dev	3.505
Minimum	0.0	Maximum	29.000		

Valid Cases 82 Missing Cases 5

FIGURE 10.

YEAR FIRST NON-DISPENSING ACC OPENED

Value Label	Value	Frequency	Valid Percent	Cum Percent
	1967	1	1.1	1.1
	1971	1	1.1	2.2
	1977	1	1.1	3.3
	1978	1	1.1	4.3
	1979	2	2.2	6.5
	1980	3	3.3	9.8
	1981	11	12.0	21.7
	1982	17	18.5	40.2
	1983	16	17.4	57.6
	1984	24	26.1	83.7
	1985	14	15.2	98.9
	1986	1	1.1	100.0
	.	4	MISSING	
	TOTAL	96	100.0	

Valid Cases 92 Missing Cases 4

FIGURE 11.

Correlations: # YEARS DISPENSING WITH AGE OF CENTER

AGE	.7202**

# of cases: 82 1-tailed Signif: * - .01 ** - .001

FIGURE 12.

Crosstabulation: AGE
By ARE PREFACI AGED PHARM DISPENSED?

Q5-> AGE	Count / Col Pct / Tot Pct	YES 1	NO 2	Row Total
0.0			1	1
			1.1	.6
			.6	
1.00		11	14	25
		13.3	15.2	14.3
		6.3	8.0	
2.00		17	24	41
		20.5	26.1	23.4
		9.7	13.7	
3.00		22	16	38
		26.5	17.4	21.7
		12.6	9.1	
4.00		12	17	29
		14.5	18.5	16.6
		6.9	9.7	
5.00		5	11	16
		6.0	12.0	9.1
		2.9	6.3	
6.00		7	3	10
		8.4	3.3	5.7
		4.0	1.7	
7.00		3	2	5
		3.6	2.2	2.9
		1.7	1.1	
8.00		2	1	3
		2.4	1.1	1.7
		1.1	.6	
9.00			1	1
			1.1	.6
			.6	
12.00		1		1
		1.2		.6
		.6		

FIGURE 12 AGE BY ARE PHARMACEUTICALS DISPENSED?

YEARS	YES	NO	
Count / Col Pct / Tot Pct 14.00	1 / 1.2 / .6		1 / .6
15.00		1 / 1.1 / .6	1 / .6
19.00		1 / 1.1 / .6	1 / .6
31.00	1 / 1.2 / .6		1 / .6
35.00	1 / 1.2 / .6		1 / .6
Column Total	83 / 47.4	92 / 52.6	175 / 100.0

FIGURE 13.

OUTSIDE PRESCRIPTIONS PER DAY

Mean	29.790	Median	20.000	Std Dev	30.905
Minimum	4.000	Maximum	200.000		
Valid Cases	81	Missing Cases	6		

FIGURE 14.

IN HOUSE PRESCRIPTIONS PER DAY

Mean	33.138	Median	18.000	Std Dev	70.674
Minimum	2.000	Maximum	600.000		
Valid Cases	80	Missing Cases	-		

FIGURE 15.

RATIO (IN-HOUSE TO OUT-HOUSE PRESCRIPTIONS)

Mean	1.605	Median	1.000	Std Dev	1.536
Minimum	.040	Maximum	10.000		
Valid Cases	79	Missing Cases	8		

FIGURE 16.

PERCENT DISPENSING REVENUE OF TOTAL REVENUE

Mean	6.444	Median	5.000	Std Dev	6.016
Minimum	1.000	Maximum	30.000		
Valid Cases	72	Missing Cases	15		

FIGURE 17.

ARE THERE PLANS TO BEGIN DISPENSING?

Value Label	Frequency	Valid Percent	Cum Percent
YES	35	48.6	48.6
NO	37	51.4	100.0
	24	MISSING	
TOTAL	96	100.0	100.0

Valid Cases 72 Missing Cases 24

FIGURE 18.

YEAR TO BEGIN DISPENSING

Value Label	Value	Frequency	Valid Percent	Cum Percent
	1986	19	95.0	95.0
	1987	1	5.0	100.0
	.	76	MISSING	
	TOTAL	96	100.0	

Valid Cases 20 Missing Cases 76

FIGURE 19.

NO. OF DIFFERENT DRUG ITEMS DISPENSED

Value Label	Value	Frequency	Percent	Valid Percent	Cum
	2	2	2.6	2.6	
	4	1	1.3	3.9	
	8	1	1.3	5.2	
	12	2	2.6	7.8	
	13	1	1.3	9.1	
	14	1	1.3	10.4	
	15	3	3.9	14.3	
	16	2	2.6	16.9	
	18	1	1.3	18.2	
	19	1	1.3	19.5	
	20	7	9.1	28.6	
	22	1	1.3	29.9	
	24	1	1.3	31.2	
	25	9	11.7	42.9	
	26	1	1.3	44.2	
	28	3	3.9	48.1	
	30	6	7.8	55.8	
	32	1	1.3	57.1	
	35	3	3.9	61.0	
	38	1	1.3	62.3	
	40	5	6.5	68.8	
	42	1	1.3	70.1	
	45	1	1.3	71.4	
	48	1	1.3	72.7	
	49	1	1.3	74.0	
	50	5	6.5	80.5	
	55	1	1.3	81.8	
	56	1	1.3	83.1	
	57	1	1.3	84.4	
	65	1	1.3	85.7	
	80	1	1.3	87.0	
	90	1	1.3	88.3	
	94	1	1.3	89.6	
	100	3	3.9	93.5	
	200	2	2.6	96.1	
	230	1	1.3	97.4	
	460	1	1.3	98.7	
	500	1	1.3	100.0	
	.	10	MISSING		
	TOTAL	87	100.0		

Mean 52.195 Median 30.000 Std Dev [illegible]

Valid Cases 77 Missing Cases 10

FIGURE 20.

PLAN TO INCREASE NO DRUGS DISPENSED?

Value Label	Frequency	Valid Percent	Cum Percent
YES	22	27.8	27.8
NO	57	72.2	100.0
	8	MISSING	
TOTAL	87	100.0	100.0

Mean 1.722 Median 2.000 Std Dev .451

Valid Cases 79 Missing Cases 8

FIGURE 21.

DRUG 1

Value Label	Frequency	Valid Percent
AMOXICILLIN	27	33.3
ERYTHROMYCIN	8	9.9
AMOXIL	7	8.6
PENICILLIN VK	7	8.6
AMPICILLIN	4	4.9
EES-400	3	3.7
RUFEN TABLETS	3	3.7
TYLENOL	3	3.7
TYLENOL & CODEINE	3	3.7
DURICEF 500	2	2.5
E-MYCIN	2	2.5
MOTRIN TABLETS	2	2.5
ACETAMINOPHEN	1	1.2
BROMATAPP	1	1.2
DICLOXACILLIN	1	1.2
DIZEPAM	1	1.2
GARAMYCIN OTIC	1	1.2
GENOPTIC OTIC SOL	1	1.2
IBUPROFEN	1	1.2
NAPROSYN	1	1.2
TETRACYCLINE	1	1.2
VIBRA-TABS	1	1.2
	6	MISSING
TOTAL	87	100.0

Valid Cases 81 Missing Cases 6

FIGURE 22.

DRUG 2

Value Label	Frequency	Valid Percent
ERYTHROMYCIN	13	16.3
AMOXICILLIN	11	13.8
PENICILLIN VK	11	13.8
EES-400	6	7.5
AMOXIL	4	5.0
AMPICILLIN	4	5.0
DARVOCET	2	2.5
E-MYCIN	2	2.5
FLEXERIL TABLETS	2	2.5
MOTRIN TABLETS	2	2.5
TYLENOL	2	2.5
TYLENOL & CODEINE	2	2.5
ACETAMINOPHEN	1	1.3
BLINX EYE WASH	1	1.3
ERYC	1	1.3
ENTEX LA	1	1.3
GUIATUSS DAC	1	1.3
IBUPROFEN	1	1.3
KEFLEX	1	1.3
NAPROSYN	1	1.3
NEAFET	1	1.3
NOVAHISTINE	1	1.3
ORPHENADRINE CITRATE	1	1.3
PARAFON FORTE TABLET	1	1.3
ROBITUSSIN	1	1.3
SODIUM SULAMID OTIC	1	1.3
SEPTRA DS TABLETS	1	1.3
SYMMETREL	1	1.3
TRIMALIN	1	1.3
ULTRACEF	1	1.3
VICODIN TABLETS	1	1.3
	.	MISSING
TOTAL	87	100

Valid Cases 80 Missing Cases 7

FIGURE 23.

DRUG 3

Value Label	Frequency	Percent
PENICILLIN VK	10	12.8
TYLENOL ...	7	9.0
AMOXICILLIN	6	7.7
ERYTHROMYCIN	5	6.4
EES-400	4	5.1
DURICEF 500	3	3.8
FLEXERIL TABLETS	3	3.8
IBUPROFEN	3	3.8
MOTRIN TABLETS	3	3.8
AMPICILLIN	2	2.6
ACETAMINOPHEN	2	2.6
ERYC	2	2.6
KEFLEX	2	2.6
TYLENOL & CODEINE	2	2.6
NAPROX	1	1.3
AMOXIL	1	1.3
ACTIFED	1	1.3
ANALGESIC BALM	1	1.3
DIPHENHYDRAMINE ELIX	1	1.3
ENTEX LA	1	1.3
EZAL	1	1.3
EMPIRIN	1	1.3
ERY-TAB TABLETS	1	1.3
GUAIFENESIN SYRUP	1	1.3
HISTALET FORTE TABS	1	1.3
HYCOMAN	1	1.3
MEL...L TABS	1	1.3
PARAFON FORTE TABLET	1	1.3
PHENERGAN & CODEINE	1	1.3
PEDIAZOLE	1	1.3
PREDNISONE TABS	1	1.3
PRED FORTE 1% SUSP	1	1.3
ROBITUSSIN	1	1.3
SEPTRA DS TABLETS	1	1.3
SOMA WITH CODEINE	1	1.3
TETRACYCLINE	1	1.3
TAGAMET	1	1.3
VICODIN TABLETS	1	1.3
	0	MISSING
TOTAL	87	100.0

Valid cases 78 Missing cases 9

FIGURE 24.

MANUFACTURER 1

Value Label	Frequency	Percent
PARKE-DAVIS	21	25.9
BIOCRAFT LABS	13	16.0
DANBURY	8	9.9
BEECHAM	6	7.4
OTHER	5	6.2
MCNEIL CONSUMER PROD	3	3.7
ABBOTT	2	2.5
AMERICAN PHARMACY	2	2.5
BOOTS	2	2.5
GOLDLINE	2	2.5
LEDERLE	2	2.5
MEAD-JOHNSON	2	2.5
MCNEIL PHRM.	2	2.5
UPJOHN	2	2.5
ALLERGAN	1	1.2
BARR PHARM.	1	1.2
LILLY	1	1.2
PFIZER	1	1.2
ROCHE	1	1.2
SCHERING	1	1.2
SYNTEX	1	1.2
STEWART JACKSON	1	1.2
WYETH	1	1.2
	6	MISSING
TOTAL	87	100.0

Valid Cases 81 Missing Cases 6

FIGURE 25.

MANUFACTURER 2

Value Label	Frequency	Percent
BIOCRAFT LABS	12	15.9
PARKE-DAVIS	11	13.8
DANBURY	10	12.5
ABBOTT	7	8.8
OTHER	5	6.3
BEECHAM	4	5.0
UPJOHN	4	5.0
MCNEIL PHRM.	3	3.8
AMERICAN PHARMACY	2	2.5
LILLY	2	2.5
MCNEIL CONSUMER PROD	2	2.5
MERCK SHARP DOHME	2	2.5
BRISTOL-MYERS	1	1.3
BURROUGHS-WELCOME	1	1.3
BARNES-HIND	1	1.3
DISTA	1	1.3
ENDO PHARM.	1	1.3
GOLDLINE	1	1.3
KNOLL	1	1.3
LEDERLE	1	1.3
MERRELL DOW	1	1.3
NORWICH-EATON	1	1.3
PAR PHARM.	1	1.3
ROBINS	1	1.3
SCHERING	1	1.3
SYNTEX	1	1.3
STEWART JACKSON	1	1.3
WYETH	1	1.3
	-	MISSING
	TOTAL 87	100

Valid Cases 80 Missing Cases 7

FIGURE 2e.

MANUFACTURER 3

Value Label	Frequency	Percent
BIOCRAFT LABS	7	9.0
MCNEIL CONSUMER PROD	7	9.0
PARKE-DAVIS	7	9.0
AMERICAN PHARMACY	6	7.7
ABBOTT	5	6.4
DANBURY	5	6.4
UPJOHN	4	5.1
BURROUGHS-WELCOME	3	3.8
MEAD-JOHNSON	3	3.8
MERCK SHARP DOHME	3	3.8
DISTA	2	2.6
GOLDLINE	2	2.6
OTHER	2	2.6
MCNEIL PHRM.	2	2.6
PHILIPS ROXANE	2	2.6
RUGBY	2	2.6
ALLERGAN	1	1.3
BEECHAM	1	1.3
BOOTS	1	1.3
ENDO PHARM.	1	1.3
IDE	1	1.3
KNOLL	1	1.3
LEMON	1	1.3
LEDERLE	1	1.3
NORWICH-EATON	1	1.3
ROSS	1	1.3
ROSINS	1	1.3
SCIE-PROVIDENT	1	1.3
SMITH KLINE & FRENCH	1	1.3
STEWART JACKSON	1	1.3
WYETH	1	1.3
WALLACE	1	1.3
	9	MISSING
TOTAL	87	100.0

Valid Cases: 78 Missing Cases: 9

FIGURE 27.

NAME OF LOCAL SUPPLIER

Value Label	Frequency	Valid Percent	Cum Percent
LOCAL PHARMACY	11	35.5	35.5
STAT-PAK	4	12.9	48.4
J J SALON	2	6.5	54.8
SOUTHWOOD	2	6.5	61.3
GEER	1	3.2	64.5
PSS	1	3.2	67.7
ULTRA DRUG	1	3.2	71.0
STEWART-JACKSON	1	3.2	74.2
SHADYSIDE PHARMACY	1	3.2	77.4
JONES DRUG CO.	1	3.2	80.6
APPLETON MEDICAL CTR	1	3.2	83.9
CROAN PHARMACY	1	3.2	87.1
HUNISTON-KEELING	1	3.2	90.3
PHARMEDIX	1	3.2	93.5
MCQUEARYS	1	3.2	96.8
COURTLAND PHARMACY	1	3.2	100.0
	56	MISSING	
TOTAL	87	100.0	

Valid Cases 31 Missing Cases 56

FIGURE 28.

NAME OF REGIONAL SUPPLIER

Value Label	Frequency	Valid Percent	Cum Percent
PHYSICIAN PHARM. SVC	3	14.3	14.3
MPI	3	14.3	28.6
PHYSICIAN FORMULARY	2	9.5	38.1
REDI MED	2	9.5	47.6
CONVENTIENCE	2	9.5	57.1
DS	1	4.8	61.9
ECHAN	1	4.8	66.7
MDS	1	4.8	71.4
H.J. HAWKINS	1	4.8	76.2
M.L. MOORE	1	4.8	81.0
STAT-PAK	1	4.8	85.7
PCY	1	4.8	90.5
WYETH	1	4.8	95.2
SOUTHWOOD DRUGS	1	4.8	100.0
	66	MISSING	
TOTAL	87	100.0	

Valid Cases 21 Missing Cases 66

-74-

FIGURE 29.

NAME OF NATIONAL SUPPLIER

Value Label	Frequency	Valid Percent	Cum Percent
PHYSICIAN PHARM. SVC	6	25.0	25.0
[illegible]	5	20.8	45.8
CONVENIENCE	3	12.5	58.3
PARKE-DAVIS	2	8.3	66.7
B & B DRUGS	1	4.2	70.8
STAK-PAK	1	4.2	75.0
GOLDLINE	1	4.2	79.2
BUYS IN BULK	1	4.2	83.3
REDI MED	1	4.2	87.5
PHARM. CORP. OF AMER	1	4.2	91.7
PHARMEDIX	1	4.2	95.8
BEECHAM	1	4.2	100.0
	63	MISSING	
TOTAL	87	100.0	

Valid Cases 24 Missing Cases 63

FIGURE 30.

OTHER SUPPLIER

Value Label	Frequency	Valid Percent	Cum Percent
ON-SITE PACKAGING	3	60.0	60.0
PRE-PAK FROM MFG	1	20.0	80.0
HOSPITAL	1	20.0	100.0
	82	MISSING	
TOTAL	87	100.0	

Valid Cases 5 Missing Cases 82

FIGURE 31

$ AVERAGE INVENTORY PREPACKAGED PHARM

Mean	[illegible]	Median	1500.000	Std Dev	10826.746
Minimum	90.000	Maximum	90000.000		

Valid Cases [illegible] Missing Cases 17

IGURE 32.

Correlation: $ AVERAGE INVENTORY PHARMACEUTICALS WITH YEARS DISPENSING

DISPENSE .2501

N of cases: 74 1-tailed Signif: * - .01 ** - .001

FIGURE 33.

PERCENT BRAND NAME DISPENSED

Mean	37.290	Median	25.000	Std Dev	29.602
Minimum	1.000	Maximum	100.000		
Valid Cases	69	Missing Cases	18		

FIGURE 34.

PERCENT GENERICS DISPENSED

Mean	69.819	Median	80.000	Std Dev	26.589
Minimum	7.000	Maximum	100.000		
Valid Cases	72	Missing Cases	15		

FIGURE 35.

PERCENT PER MONTH INCREASE

Value Label	Value	Frequency	Valid Percent	Cum Percent
	1	4	10.3	10.3
	2	4	10.3	20.5
	3	4	10.3	30.8
	4	1	2.6	33.3
	5	8	20.5	53.8
	6	1	2.6	56.4
	7	1	2.6	59.0
	8	1	2.6	61.5
	10	11	28.2	89.7
	20	2	5.1	94.9
	25	1	2.6	97.4
	50	1	2.6	100.0
	.	48	MISSING	
	TOTAL	87	100.0	

Valid Cases 39 Missing Cases .0

FIGURE 36.

PERCENT PER MONTH INCREASE

Mean	7.615	Median	5.000	Std Dev	6.851
Minimum	1.000	Maximum	30.000		

Valid Cases 39 Missing Cases 48

FIGURE 37.

Correlations: IN-HOUSE PRESCRIPTIONS/DAY WITH $AVERAGE INVENTORY PHARMACEUTICALS

015 .8793**

N of cases: 71 1-tailed Signif: * - .01 ** - .001

FIGURE 38.

$AVERAGE PHARMACEUTICAL INVENTORY BY AVERAGE IN-HOUSE PRESCRIPTIONS

	IN-HOUSE PRESCRIPTION		
$AVG	MEAN	MEDIAN	N
1-999	20.4	10	18
1000-1999	20.2	23	17
2000-5000	29.8	22	10
5000	111.3	45	8

FIGURE 39.

FIGURE: YEARS DISPENSING BY $AVERAGE PHARMACEUTICAL INVENTORY AND AVERAGE IN-HOUSE PRESCRIPTIONS

	$ AVG. PHARMACEUTICALS			# IN-HOUSE PRESCRIPTIONS		
YEARS	MEAN	MEDIAN	N	MEAN	MEDIAN	N
1	2077	1500	11	24.1	20	10
2	2303	1800	11	20.7	15	10
3	2091	1800	11	16.5	10	10
4-5	1625	2375	8	66.5	20	6
6	4000	1800	1	30.0	30	1

FIGURE 40.

ARE PHARMACISTS EMPLOYED?

Value Label	Frequency	Valid Percent	Cum Percent
YES	7	8.5	8.5
NO	75	91.5	100.0
	5	MISSING	
TOTAL	87	100.0	

Valid Cases 82 Missing Cases 5

FIGURE 41.

PART-TIME PHARMACIST EMPLOYED?

Value Label	Frequency	Valid Percent	Cum Percent
YES	4	8.5	8.5
NO	43	91.5	100.0
	40	MISSING	
TOTAL	87	100.0	

Valid Cases 47 Missing Cases 40

FIGURE 42.

FULL-TIME PHARMACIST EMPLOYED?

Value Label	Frequency	Valid Percent	Cum Percent
YES	3	6.5	6.5
NO	43	93.5	100.0
	41	MISSING	
TOTAL	87	100.0	

Valid Cases 46 Missing Cases 41

FIGURE 43.

WHO DISPENSES PHARMACEUTICALS IN YOUR ACC?

Value Label	Frequency	Valid Percent	Cum Percent
FULL-TIME PHYSICIAN	38	48.1	50.6
PART-TIME PHYSICIAN	3	3.8	54.4
FULL-TIME ASSISTANT	1	1.3	55.7
FULL-TIME NURSE	12	15.2	70.9
ONE AND TWO ABOVE	9	11.4	82.3
ONE AND THREE ABOVE	5	6.3	88.6
ONE AND FOUR ABOVE	9	11.4	100.0
	9	MISSING	
TOTAL	87	100.0	

Valid Cases 79 Missing Cases 8

FIGURE 44.

DOES DISPENSING INCREASE PATIENT CENSUS?

Value Label	Frequency	Valid Percent	Cum Percent
YES	28	35.0	35.0
NO	52	65.0	100.0
	7	MISSING	
TOTAL	87	100.0	

Valid Cases 80 Missing Cases 7

FIGURE 45.

DOES DISPENSING INCREASE PATIENT SATISFACTION?

Value Label	Frequency	Valid Percent	Cum Percent
YES	82	94.3	94.3
NO	5	5.7	100.0
TOTAL	87	100.0	

Valid Cases 87 Missing Cases 0

FIGURE 46.

REASON FOR DISPENSING—
"CONVENIENCE TO PATIENTS"

Value Label	Frequency	Valid Percent	Cum Percent
RANKED NUMBER 1	61	72.6	72.6
RANKED NUMBER 2	19	22.6	95.2
RANKED NUMBER 3	4	4.8	100.0
	3	MISSING	
TOTAL	87	100.0	

Valid Cases 84 Missing Cases 3

FIGURE 47.

REASON FOR DISPENSING—
"SERVICE TO ATTRACT PATIENTS"

Value Label	Frequency	Valid Percent	Cum Percent
RANKED NUMBER 1	5	8.5	8.5
RANKED NUMBER 2	23	39.0	47.5
RANKED NUMBER 3	28	47.5	94.9
RANKED NUMBER 4	2	3.4	98.3
RANKED NUMBER 5	1	1.7	100.0
	28	MISSING	
TOTAL	87	100.0	

Valid Cases 59 Missing Cases 28

FIGURE 48.

REASON FOR DISPENSING—
"COMPETITORS WERE DOING IT"

Value Label	Frequency	Valid Percent	Cum Percent
RANKED NUMBER 1	1	2.9	2.9
RANKED NUMBER 2	2	5.7	8.6
RANKED NUMBER 3	7	20.0	28.6
RANKED NUMBER 4	23	65.7	94.3
RANKED NUMBER 5	2	5.7	100.0
	52	MISSING	
TOTAL	87	100.0	

Valid Cases 35 Missing Cases 52

FIGURE 49.

REASON FOR DISPENSING--
"SOURCE OF ADDITIONAL REVENUE"

Value Label	Frequency	Valid Percent	Cum Percent
RANKED NUMBER 1	16	21.6	21.6
RANKED NUMBER 2	32	43.2	64.9
RANKED NUMBER 3	19	25.7	90.5
RANKED NUMBER 4	6	8.1	98.6
RANKED NUMBER 5	1	1.4	100.0
	13	MISSING	
TOTAL	87	100.0	

Valid Cases 74 Missing Cases 13

FIGURE 50.

REASON FOR DISPENSING--
"OTHER REASON"

Value Label	Frequency	Valid Percent	Cum Percent
RANKED NUMBER 1	2	22.2	22.2
RANKED NUMBER 2	2	22.2	44.4
RANKED NUMBER 3	4	44.4	88.9
RANKED NUMBER 4	1	11.1	100.0
	78	MISSING	
TOTAL	87	100.0	

Valid Cases 9 Missing Cases 78